SUMMARY STATEMENT

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(Privileged Communication)

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Application Number: **2 P30 CA168524-11**
Formerly: **3P30CA168524-09**

Principal Investigator

JENSEN, ROY A.

Applicant Organization: UNIVERSITY OF KANSAS MEDICAL CENTER

Review Group: **NCI-A**
Cancer Centers Study Section (A)
Dr. Roy A. Jensen (2 P30CA168524-11)

Meeting Date: **05/12/2022**
Council: **MAY 2022**
Requested Start: **07/01/2022**

RFA/PA: **PAR20-043**
PCC: **1XMD**

Project Title: **The University of Kansas Cancer Center**

SRG Action: **Impact Score:20**
Next Steps: **Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects: **30-Vertebrate animals involved - no SRG concerns noted**
Gender: **1A-Both genders, scientifically acceptable**
Minority: **1A-Minorities and non-minorities, scientifically acceptable**
Age: **1A-Children, Adults, Older Adults, scientifically acceptable**

Project Year	Direct Costs Requested	Estimated Total Cost
11	1,705,000	2,645,792
12	1,704,999	2,645,790
13	1,704,999	2,645,790
14	1,704,998	2,645,788
15	1,704,999	2,645,790
TOTAL	8,524,995	13,228,950

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

RESUME AND SUMMARY OF DISCUSSION: In this renewal Cancer Center Support Grant (CCSG) application submitted by the University of Kansas Cancer Center (KUCC), the goals are to leverage unique regional scientific assets to build a nationally significant cancer research center that will become a leading institution to transform discoveries in the laboratory into new therapeutic approaches in order to meet the needs of the more than 4.5 million Americans who live within the 92,000 square miles of the KUCC catchment area. The CCSG application proposes three research programs; a shared resource management and seven shared resources plus one developing resource; Clinical Protocol and Data Management; Protocol Review and Monitoring System; Cancer Research Training and Education Coordination, Community Outreach and Engagement; Leadership, Planning, and Evaluation; Administration; and Developmental Funds. The KUCC requests five years of support and to become NCI-designated comprehensive consortium cancer center.

Cancer Biology (CB) Program, co-led by Drs. Kristi Neufeld, Linheng Li, Tomoo Iwakuma, and Sufi Thomas is rated in the outstanding to excellent range. Key accomplishments include the identification of tumor microenvironment, mitochondrial, and oncogenic factors that affect tumor behavior and contributing to the development of clinical trials being conducted in the Drug Discovery, Delivery, and Experimental Therapeutics (D3ET) and Cancer Prevention and Control Program (CPC) programs. The CPC Program co-led by Drs. Edward Ellerbeck, Nicole Nollen, and Jennifer Klemp, is rated as exceptional. Notable research includes work on tobacco cessation in African Americans, obesity treatment in rural primary care settings, and HPV/cervical cancer prevention. Additional translational work focuses on novel preventive interventions for breast cancer and studies of the impact of weight loss on markers of immune function in men with prostate cancer. The D3ET Program co-led by Drs. Priyanka Sharma, Dan Dixon, and John Taylor is rated as outstanding. Important accomplishments include advancement of three KU-invented small-molecule drugs and two cell-based therapies into clinical development. This program has a strong pipeline of compounds under development.

Shared Resources Management, led by the Associate Director, Dr. Matthew Mayo, is rated excellent to outstanding. The KUCC shared resources are managed effectively. Each of the shared resources are used by the members of the KUCC including consortium partners and meet members' needs. However, the oversight for individual shared resources is not well defined. The shared resources led by qualified core directors are cost effective. The ratings for the shared resources are as follows: Biospecimen Shared Resource is rated exceptional; Biostatistics and Informatics, Clinical Pharmacology, Lead Development, and Optimization; and Transgenic and Gene-Targeting Shared Resources are each rated as outstanding; Nutrition Shared Resource is rated as excellent, and the Flow Cytometry Shared Resource is rated in the excellent to very good range.

The Cancer Research Training and Education Coordination (CRTEC) led by Dr. Danny Welch, is rated in the outstanding to excellent range. The CRTEC at KUCC was instrumental in creating three new graduate programs and has developed several innovative educational initiatives. A notable strength of the CRTEC is the bidirectional education efforts to engage learners in community outreach.

Community Outreach and Engagement (COE), led by Dr. Ronald Chen, is rated as exceptional. Strengths of COE include creation of the OPTIK database, the partnership with community including the Masonic Cancer Alliance, the deep engagement with patient advocates, and dedication to a focus on rural and low-income communities. There is evidence of extended reach within and beyond the catchment area through participation by KUCC members in regional and national organizations to advance policy.

The Clinical Protocol and Data Management (CPDM), led by Medical Director Tara Lin MD and Natalie Streeter RN, MSN is rated outstanding. Overall accrual to clinical trials, both interventional and non-interventional, is reasonable and increasing. Inclusion of Women in Clinical Research, Inclusion of Minorities in Clinical Research, and Inclusion of Individuals Across the Lifespan in Clinical Research, and the Data and Safety Monitoring are each rated Acceptable. The Protocol Review and Monitoring System, led by Dr. Qamar Khan, is rated satisfactory. The clearly defined two-step review process is fundamentally adequate. However, given the relatively low rate of disapprovals, a concern is the overall rigor of the initial and second stages of protocol review.

Developmental Funds, led by Dr. Andrew Godwin, is rated outstanding. During the current funding period, KUCC invested in 24 pilot projects totaling $779,626 with a robust return on investment (ROI) of $6.9 million in extramural funding and 69 peer-reviewed publications. In addition to CCSG funds, the institution committed an additional $800,056 for 27 awards with ROI of $10 million in extramural funds and 30 additional peer-reviewed articles. Support for two proposed staff investigators, Drs. Baranda and Calhoun, is acceptable.

Leadership, Planning and Evaluation is rated Outstanding. Led by Dr. Jensen with superb credentials, KUCC has achieved major growth and advances. Many accomplishments by the KUCC senior leadership team are evident, although the impact of strategic efforts remains unclear.

Administration, led by the Associate Director, Ms. Teresa Christenson, is rated excellent to outstanding. Sufficient fiscal and programmatic oversight for finances, shared resources, consortium partners, faculty recruitment, informatics, technology transfer, compliance, contracting, and support to research programs and shared resource directors are in place. However, there were inconsistencies in data and metrics across some components in the written application.

The six Essential Characteristics of the cancer center are fulfilled and are rated as follows: Physical Space is rated in the outstanding to exceptional range; Organizational Capabilities is rated as outstanding, Transdisciplinary Collaboration and Coordination is rated as outstanding, Cancer Focus is rated as outstanding, Institutional Commitment is rated as Exceptional, and the Center Director is rated Exceptional.

In summary, with robust institutional support, a strong science base, and remarkable leadership of Dr. Roy Jensen who is eminently qualified to lead the Cancer Center, this comprehensive KUCC with its consortium partners is well poised to continue in an upward trajectory to make strong impact on the cancer burdens in the State of Kansas and beyond. Support for the requested five years is appropriate.

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OVERALL DESCRIPTION (provided by applicant): The University of Kansas Cancer Center (KUCC) is a matrix consortium cancer center that includes: The University of Kansas Medical Center (KUMC), the University of Kansas in Lawrence (KU-L) and via consortium agreement, the Stowers Institute for Medical Research (Stowers) and Children's Mercy (CM) Kansas City. In 2020, 171 members of KUCC accounted for $9.7M of NCI funding and a total of $57M in overall cancer-related funding, an increase of $8M since the last CCSG submission. Supported by an experienced, nationally recognized leadership team, Roy A. Jensen, MD, has led KUCC on a strong upward trajectory that has been catalyzed by over $467M philanthropic support since 2004. Over the last four years, substantial progress has been made broadening partnerships with communities throughout the KUCC catchment area, recruiting highly innovative physician-scientists, and expanding clinical research and early phase clinical trials. We have also been advancing education for the next generation of scientists and healthcare providers and heightening the influence of KUCC researchers in the national scientific community. KUCC has established five aims to ensure KUCC leads in the fight against cancer: 1. Leverage unique regional assets to transform research discoveries from the laboratory and the clinic to drive new anticancer therapeutic development. 2. Provide the optimal environment to focus the power of precision medicine, basic science inquiry, drug discovery and development, and behavioral interventions to decrease cancer incidence, morbidity, and mortality. 3. Lead and implement a comprehensive strategy to educate both the current and next generation of cancer researchers and clinicians in cancer research, treatment, prevention, and control. 4. Partner with key stakeholders, community advocates and regional leaders to develop, promote, and foster research-based cancer prevention, diagnosis, treatment, control, and survivorship strategies to enhance our national impact, improve cancer outcomes and ensure health equity. 5. Advance team science by fostering innovative partnerships and collaborations. To accomplish these aims KUCC has three research programs: 1) Cancer Biology, 2) Cancer Prevention and Control, and 3) Drug Discovery, Delivery and Experimental Therapeutics. In addition, KUCC supports the Clinical Trials Office, seven established shared resources – Biospecimen, Biostatistics and Informatics, Clinical Pharmacology, Flow Cytometry, Lead Development and Optimization, Nutrition, and Transgenic and GeneTargeting – and one developing shared resource – Microscopy & Analytical Imaging.

CRITIQUE:

OVERALL CRITIQUE:

Criterion Scores:

	Significance	Investigator	Innovation	Approach	Environment
Reviewer 1	1	2	2	2	1
Reviewer 2	1	2	2	2	1
Reviewer 3	1	2	2	3	1

The University of Kansas Cancer Center is a matrix cancer center which received its NCI-designation in 2012. In this competing renewal application for a Cancer Center Support Grant, five years of support is requested for three research programs; shared resource management and seven shared resources plus one developing resource; Clinical Protocol and Data Management; Protocol Review and Monitoring System; Cancer Research Training and Education Coordination, Community Outreach and Engagement; Leadership, Planning, and Evaluation; Administration; and Developmental Funds. KUCC

includes two consortium partners, the Stowers Institute for Medical Research and the Children's Mercy Hospital, Kansas City.

The overall mission of the KUCC is "To be a world-class cancer center that is at the forefront of discovery, development, and implementation of knowledge, technology, and novel therapeutic agents for the prevention and treatment of cancer." Roy Jensen MD has served as Director since 2004. During the current funding period, he oversaw the creation and implementation of a new strategic plan and has orchestrated the growth and expanded impact of the cancer center. The current KUCC senior leadership team includes a Deputy Director and eight Associate Directors (ADs) with new appointments to the roles of AD for Basic Science (Dr. Anant), AD for Cancer Prevention and Survivorship (Dr. Belfort), AD for Clinical Research (Dr. Sun), and AD for Health Equity (Dr. Chen). All AD roles are well delineated and justified.

There are currently 171 members of KUCC representing a small reduction in membership since 2016 due to more rigorous membership review. In 2021, KUCC members held $51.2 million (direct costs) in total cancer-related funding and $35 million (direct costs) in peer-reviewed funding, of which $10.1 million is NCI funding. This represents an increase in total and NCI funding in the current period. Members hold an additional $3.4 million in training grants in addition to the CCSG award. During the current funding period, the KUCC recruited 41 external faculty members. Notable scientific strengths of KUCC include a robust drug discovery and development platform fostering the progression of five KUCC-developed anti-cancer agents to clinical trials, translational research on novel circulating exosome biomarkers for early detection of ovarian cancer, molecular mechanisms of immune escape and therapeutic strategics to overcome therapy resistance, novel prevention studies in women at increased risk for breast cancer, and community-based research to reduce tobacco use and obesity.

Improvements in collaborative research are reflected in increases in publication metrics (CY21 data), with strong metrics for intra-programmatic (25-31%), inter-programmatic (18-22%), and inter-institutional (53-70%) collaborations. Of 688 peer reviewed publications in 2021, 12% appear in journals with impact factors $\geq$10. There has also been a notable increase in multi-investigator grants from 42 to 60. These multi-investigator grants, and collaborative publications reflect the Center's focused efforts to enhance collaborative research. Accruals to interventional therapeutic trials have increased relative to the prior grant period with steady growth in investigator-initiated trials, despite the COVID-19 pandemic.

The KUCC defines its catchment area as the state of Kansas as well as 18 neighboring counties in western Missouri, with a total population of 4.5 million of which ~1 million live in rural/frontier areas. Eighty-five percent of the residents of the catchment population are white, 8% are African American, and 10% are Hispanic. Utilizing a cancer demographics database, and with input from the Community Advisory Board, the priority cancers for KUCC research and outreach include tobacco-related cancers, breast, gastrointestinal, prostate, and hematologic malignancies; obesity is also a catchment area priority. The Masonic Cancer Alliance (MCA), established in 2007 as the community outreach and engagement arm of KUCC, fosters execution of KUCC's outreach efforts, including bidirectional communication with constituencies in the catchment area.

The KUCC's program structure includes three research programs: Cancer Biology (CB), Cancer Prevention and Control (CPC), and Drug Discovery, Delivery and Experimental Therapeutics (D3ET). With input from the KUCC EAB, leadership merged the former Cancer Prevention and Survivorship and Cancer Control and Population Health programs into the new CPC program with several members

being reassigned to the CB program. With this programmatic reorganization, there were several new internal program leader appointments: Dr. Nolan was added as coleader of CPC, Drs. Thomas and Iwakuma were added as co-leaders of CB, and Dr. Sharma was added as a coleader of D3ET. The current KUCC programs now have multiple co-leaders, with four for CB and three each for CPC and D3ET.

The Cancer Biology (CB) Program with 59 members is led by Drs. Neufeld, Li, Thomas, and Iwakuma and is rated Outstanding to Excellent. There are two specific aims: (1) Promote and facilitate collaboration within and outside the program to enhance discovery and (2) Leverage basic science discoveries to inspire pre-clinical and clinical development of novel therapies, diagnostics, and prevention strategies. The program has approximately $10.2 million (direct) in peer-reviewed funding, with approximately $1.4 million from the NCI. Inter-programmatic and intra-programmatic publications are strong at 22% and 28%, respectively, with 13% of publications in high impact journals (≥10 Impact Factor). Key accomplishments include identifying tumor microenvironment, mitochondrial, and oncogenic factors that affect tumor behavior and contributing to the development of clinical trials being conducted in the D3ET and CPC programs. Program members benefit from KUCC shared resources and pilot funding opportunities, and their research focuses on catchment area needs, demonstrating strong value added. A weakness is the continued lack of multi-project grants.

The Cancer Prevention and Control Program (CPC) is rated Exceptional. CPC has 49 members and is capably led by Drs. Ellerbeck, Klemp, and Nollen. Excluding training grants, the program has approximately $12.5 million (direct) in peer-reviewed funding, with approximately $3.8 million from the NCI. The aims (themes) of the program are primary prevention, prevention in high-risk populations, and survivorship. Program members have 16 multi-PI R01 grants, which reflects well on the program. The program has a strong publication record, with 225 publications in 2020, 9% of which are in high-impact journals. Inter-programmatic and intra-programmatic publications are strong at 20% and 32%, respectively. The program has sufficient breadth and depth, with notable work on tobacco cessation in African Americans, obesity treatment in rural primary care settings, and HPV/cervical cancer prevention. Additional translational work focuses on novel preventive interventions for breast cancer and studies of the impact of weight loss on markers of immune function in men with prostate cancer. Overall, CPC is making critical contributions to the Center's continued success on impacting the cancer burden in the catchment area. There are opportunities to expand inter-programmatic projects with external funding.

The Drug Discovery, Delivery and Experimental Therapeutics Program (D3ET) is rated Outstanding. Led by Drs. Taylor, Dixon, and Sharma, D3ET is the key translational and clinical research program at KUCC. The program has three scientific themes: 1) Drug Discovery and Delivery; 2) Drug and Diagnostic Development; and 3) Evaluation of New Cancer Treatment Strategies in Experimental Therapeutic Trials. The D3ET program has approximately $9.9 million (direct) in peer-reviewed funding, with approximately $4.8 million from the NCI, representing impressive growth in funding. There are also significant increases in the numbers of and accrual to investigator-initiated clinical trials. Members are highly productive, with 902 publications of which 33% are intra-programmatic, 21% are inter-programmatic publications, and 142 publications are in high-impact journals. Selected accomplishments of the program members include advancement of three KU-invented small-molecule drugs and two cell-based therapies into clinical development. This program also has a strong pipeline of compounds in development, with great promise for achieving further therapeutic advances.

Shared Resources Management is rated Excellent to Outstanding. The AD for Shared Resources, Dr. Mayo has appropriate experience in academic leadership and shared resource leadership. KUCC shared resources are managed effectively, are each used by the members of the KUCC including consortium partners and appear to meet members' needs. However, the oversight for individual shared resources is not described thoroughly. While this was partially explained at the site visit in terms of how often the internal advisory boards meet, it was still not entirely clear how the input is utilized from these advisory boards to institute improvements. There was also unevenness in the strength of the individual shared resources: Biospecimen Shared Resource, Exceptional; Biostatistics and Informatics Shared Resource, Outstanding; Clinical Pharmacology Shared Resource, Outstanding; Flow Cytometry Shared Resource, Excellent to Very Good; Lead Development and Optimization Shared Resource, Outstanding; Nutrition Shared Resource, Excellent; and Transgenic and Gene-Targeting Shared Resource, Outstanding. A developing Microscopy and Analytic Shared Resource is anticipated to benefit members' research and KUCC science.

The Cancer Research Training and Education Coordination (CRTEC) component is led by Drs. Welch and Harlan-Williams and is rated Outstanding to Excellent. The CRTEC is a new programmatic initiative of the KUCC and coordinates and provides cancer-focused education, training, and career enhancement to over 500 trainees and ~200 healthcare professionals annually. The CRTEC participates in 24 actively funded training projects with total direct cost funding of approximately $3.4 million. The KUCC was instrumental in creating three new graduate programs and has developed several innovative educational initiatives including the Accelerate Cancer Education (ACE) program for underrepresented high school students and the Grant Rounds forum to assist junior investigators in the development of grant proposals. An additional strength of the CRTEC is the bidirectional education efforts to engage learners in community outreach. Weaknesses include unclear metrics for measuring the success of efforts to increase cancer-specific training and career enhancement and opportunities to enhance educational efforts and mentorship across the research programs.

Community Outreach and Engagement (COE), led by Dr. Chen, is rated Exceptional. The KUCC serves a catchment area that includes the entire state of Kansas plus 18 neighboring counties in western Missouri, with a total population of 4.5 million of which ~1 million live in rural/frontier areas. Eighty-five percent of the residents of the catchment population are white, 8% are African American, and 10% are Hispanic. Strengths of COE at KUCC include creation of the OPTIK database, the partnership with the Masonic Cancer Alliance and other community partners, deep engagement of patient advocates, and dedication to a focus on rural and low-income communities. There is evidence of extended reach within and beyond the catchment area through participation by KUCC members in regional and national organizations to advance policy. Cancer screening is imperative and at the site visit, clear plans were outlined to address suspected cancer cases that may result from these screenings. There are appropriate metrics in place for evaluation and a well-formed and expansive blueprint for the future. This is an exceptional program with a solid infrastructure to continue to monitor community needs and adapt as those needs evolve.

The Clinical Protocol and Data Management (CPDM), led by Medical Director Tara Lin MD and Natalie Streeter RN, MSN is rated Outstanding. The KUCC CDPM continues to grow and adapt to the needs of the KUCC cancer clinical trials programs. The CPDM component has several strengths, with only minor weaknesses. The organizational structure and functions are comprehensive and well-coordinated. The quality control functions, and training services appear to be adequate. There are appropriate plans in place to identify impediments to successful accrual of patients. Overall, the accrual to clinical trials both interventional and non-interventional is reasonable and increasing. Minor weaknesses include

clarification of the roles of some committees, inconsistencies in the written document on accrual numbers, and opportunity to enhance timely initiation of clinical trials. Future plans and directions are well-articulated and address the anticipated increases in complexity and needs over the next five years.

Protocol Review and Monitoring System, led by Dr. Khan, is rated Satisfactory. The PRMS continues to mature and serve the center well. There is a clearly defined two-step review process which is fundamentally adequate and responsive to CCSG guidelines and the prior review. Metrics on the time to activation for various study types was provided at site visit in response to questions. There is a remaining concern regarding overall rigor of the initial and second stages of review, given the relatively low rate of disapprovals. Further, the application states that the disease working groups can terminate active trials; however, during discussion at the site visit, it appeared that this was not the case and that the PRMC has this capacity. Time to activation for most trials still require some work for further improvement.

The components Inclusion of Women in Clinical Research, Inclusion of Minorities in Clinical Research, and Inclusion of Individuals Across the Lifespan in Clinical Research, are each rated Acceptable. Accrual to interventional treatment trials is largely representative of the cancer incidence across most minority groups and there are appropriate plans and processes for monitoring, retaining, and improving recruitment of under-represented groups. Pediatric Oncology is now an expanded component of KUCC with more formalized arrangements from the time of the last review and accrual across the lifespan is appropriately described. Data and Safety Monitoring is Acceptable.

Developmental Funds, led by Dr. Godwin, is rated Outstanding. Administration has rigorous processes for the review and evaluation of pilot projects, with clear guidelines on review criteria and reporting processes. During the current project period, KUCC invested in 24 pilot projects totaling $779,626 with a robust return on investment (ROI) of $6.9 million in extramural funding and 69 peer-reviewed publications. In addition to CCSG funds, the institution committed an additional $800,056 for 27 awards returning $10,023,914 in extramural funds and 30 additional peer-reviewed articles. Support for two proposed staff investigators, Drs. Baranda and Calhoun, is acceptable; both are highly qualified with clearly delineated roles. Opportunities remain to optimize use of developmental funds to accelerate progress with KUCC’s strategic priorities and to enhance success with collaborative grants.

Leadership, Planning and Evaluation is rated Outstanding. Dr. Jensen has impeccable credentials, comprehensive authorities, and a stellar level of accomplishment which he has used skillfully to achieve major growth and advances for KUCC. He has assembled a group of Senior Leaders who are highly qualified and experienced in their respective areas of expertise, all of whom have clearly delineated roles and responsibilities. The Strategic Plan has been carefully refined and focused on the "road to comprehensive status." Overall, there are many outstanding accomplishments by the KUCC senior leadership team, although value is somewhat mitigated by a lack of clarity in the evaluation of the impact of strategic efforts against tangible metrics.

Administration is rated Excellent to Outstanding. The KUCC administrative office is led by Associate Director for Administration, Teresa J. Christenson, who reports directly to the Cancer Center Vice-Chancellor and Director. Overall, the administration team has made significant progress in developing an adequate infrastructure to run the KUCC, including its members across the consortium. There is sufficient fiscal and programmatic oversight for finances, shared resources, consortium partners, faculty recruitment, informatics, technology transfer, compliance, contracting, and support to research programs and shared resource directors. Opportunities to continue administration’s progress from the

prior submission include enhanced rigor in the cancer relevance review process, specifically in how percent of direct dollars are assigned. Further, there were inconsistencies in data and metrics across some components in the written application. Additional consideration should be given to how to best facilitate and promote metrics curation and reporting throughout the Center.

The Essential Characteristics of the cancer center are fulfilled and are rated as follows:

Physical Space is rated Outstanding to Exceptional. Comprising more than 738,000 sq ft of research and clinical space, KUCC is well positioned to accommodate the needs of faculty across the scope and breath of its research areas. Despite the geographic dispersion, there is evidence that members, independent of their location, have adequate access to all facilities and that KUCC leadership is making strong efforts to promote a culture of collaboration. There has been strategic expansion of research and clinical space to enable additional transdisciplinary/multidisciplinary research and there is a planned expansion of 670,000 ft^2 of new space to foster state of the art translational research. Although the exact timeline for construction is understandably uncertain, there is considerable confidence that this new space will open in the next grant period.

Organizational Capabilities is rated Outstanding. Overall, the organizational capabilities of the center have added significant value to the cancer mission and have fostered scientific interactions and joint initiatives among consortium partners. Significant progress is being made in aligning vision and goals. Impressive organizational inroads in aligning care across the catchment area are also evident. Strategic planning activities are evident, and various committees have been assembled to implement and evaluate the strategic plan. An extensive set of initiatives and goals are presented in the application, along with an impressive set of successful funding initiatives and achievements. Opportunities exist to foster even greater integration and coordination at consortium sites and to implement more rigorous processes for evaluating the impact of organizational efforts.

Transdisciplinary Collaboration and Coordination is rated Outstanding. There is evidence of transdisciplinary collaboration and coordination at the Center as exemplified by small but consistent improvements in collaborative publication metrics and a sizable increase in multi-investigator grants. Collaborative science has also been facilitated by investments to support translational research, and by leveraging the extensive infrastructure for cancer drug discovery and development. There are five FDA INDs based on KUCC research, including the development of Fosciclopirox and translation to clinical trials. In the next grant period, there is an opportunity to elevate the level of paradigm-shifting and clinical practice-changing research.

Cancer Focus is rated Outstanding. Overall, there is sufficient breadth, depth, and significance of the cancer-related research within the individual research programs, publications, and peer-reviewed research support. There is also evidence of improvement in cancer focus relative to the prior cycle, as reflected in grown in the KUCC cancer-related research funding base to $51.2 million and growth in oncology interventional trial accruals, particularly investigator-initiated trials. KUCC has recruited 41 new faculty members who have contributed to the growth of cancer focused research at the Center. There is an opportunity to enhance the rigor of the cancer relatedness review of grants and a need for greater clarify in how percent of direct dollars are assigned cancer relevance.

Institutional Commitment is rated Exceptional. The KUCC continues to benefit from exceptional institutional and financial support. The authorities of the Director over the institution’s cancer activities are significant and Dr. Jensen is well-positioned to advocate for the cancer mission in institution-wide committees. Excluding the $150 million for the building of the cancer-related functions of Children’s

Mercy Research Institute, there was over $300 million provided to the Cancer Center from the state, university, the health system, philanthropy, the Johnson County Research Triangle, the Masonic Cancer Alliance, Children's Mercy Hospital, and the Stower's Institute. In addition, the state of Kansas has provided $5 million annually, and beginning in 2021, this will increase to $10 million annually. Overall, the institutional support is robust, and discretionary resources under the direct control of the cancer center appear significant.

The Center Director is rated Exceptional. Dr. Jensen is deeply experienced, well situated, and superbly well qualified to lead the KUCC Cancer Center and has the appropriate authority and institutional mandate to continue to be successful in this role. In this funding period, he led the refinement of the KUCC strategic plan and the recruitment of 41 new investigators into the cancer program. Under his leadership, KUCC has increased its cancer related funding base and achieved robust inter- and intra-programmatic publication metrics. His significant contributions to the national efforts in cancer has expanded the collaborations and reach of KUCC, and deeply increased the regional impact through KUCC research and the philanthropic support of that research. He is eminently qualified to serve as KUCC's director.

In summary, the KUCC is the sole NCI-designated cancer center in the state of Kansas. The impact of the center and CCSG on the catchment area is impressive. The three research programs in the KUCC exhibit strong scientific productivity with growth in cancer related funding and accruals to clinical trials, especially investigator-initiated trials. There is evidence for collaborative interactions as exemplified by increases in collaborative publication metrics and multi-institutional grants. While there are opportunities to improve protocol review and monitoring, reduce the unevenness in shared resources, improve the rigor of cancer relatedness reviews, and enhance the tracking of evaluation data based on established metrics, the Center is moving in a very positive direction. With strong institutional support, a strong science base, and an exceptional center director, KUCC with the consortium partners is well-positioned to make a strong impact on cancer burdens in the state of Kansas and beyond. Support for the requested five years is appropriate.

IRG NOTE: In response to the Site Visit Report, written comments were received from the principal investigator on March 23, 2022. The comments and the Site Visit Report were carefully considered by the members of NCI IRG Cancer Centers Study Section (A), during the discussion, final assessment, and scoring of the application. Corrections and changes have been made, where appropriate.

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE (Also, see the heading, Data and Safety Monitoring)

DATA AND SAFETY MONITORING PLAN: ACCEPTABLE

INCLUSION OF WOMEN PLAN: ACCEPTABLE (Also, see the heading, Inclusion of Women in Clinical Research.)

INCLUSION OF MINORITIES PLAN: ACCEPTABLE (Also, see the heading, Inclusion of Minorities in Clinical Research.)

INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN PLAN: ACCEPTABLE (Also, see the heading, Inclusion of Individuals Across the Lifespan in Clinical Research.)

VERTEBRATE ANIMALS: ACCEPTABLE

BIOHAZARDS: ACCEPTABLE

ADDITIONAL REVIEW CONSIDERATIONS

COMPREHENSIVENESS:

Overall, this KUCC has significant strengths in the full spectrum of cancer research, as it relates to basic, clinical, translational, and population research. There is active collaboration between the Center's research programs and translational research has expanded, with an increased number of patients enrolled on clinical trials, along with an increased number of investigator-initiated trials. The level of transdisciplinary research and collaborative interactions has expanded as evidenced by a robust level of intra- and inter-programmatic collaborative publications and a growing number of multi-investigators, team-based grants. KUCC has a well-defined catchment area and is serving its catchment area community through multiple outreach and engagement mechanisms through its exceptional community outreach and engagement. In addition, the cancer center has a pipeline of cancer research training activities across the trainee continuum. These activities are integrated across all consortium sites. Overall, the Center fulfills the scientific requirements of comprehensiveness designation, and the research-related aspects of comprehensiveness are approved.

Assessment: Satisfactory

CONSORTIUM: The KUCC has two sites, the KUMC and KU-Lawrence; cancer-related activities at the latter focus on basic and pharmaceutical research. The two consortium partners are Stowers Institute for Medical Research (an independent free-standing basic research institute in Kansas City and a consortium partner since 2009), and Children's Mercy Hospital (CM), Kansas City (a partner since 2015). Both consortium partners meet benchmarks for funding as outlined in their MOUs - with minimum of seven R01-equivalent active grants, held by at least five independent investigators. Both sites house KUCC investigators (11 at Stowers, 16 at CM) and have individuals in leadership roles in KUCC. Stowers members teach in KUMC graduate courses, and their graduate students also take courses at KUMC. Both consortium partners have tangible and substantial commitments to KUCC and there is evidence of full integration into KUCC research programs. Adequate MOUs are in place.

Assessment: Satisfactory

RESOURCES SHARING PLANS

Data Sharing Plan: ACCEPTABLE. The application addresses the NIH Policy on Data Sharing.

Sharing of Model Organisms for Biomedical Research: ACCEPTABLE. The application addresses the NIH Policy on Sharing of Model Organisms for Biomedical Research.

Genome-Wide Association Studies (GWAS): ACCEPTABLE. The application addresses the NIH Policy on Genome-Wide Association Studies.

ADDITIONAL REVIEW CRITERIA

RESEARCH PROGRAMS

Cancer Biology Program

DESCRIPTION (provided by applicant): The Cancer Biology (CB) program represents basic science initiatives of The University of Kansas Cancer Center (KUCC), unified by member utilization of molecular, biochemical, and model organism and cell-based approaches to study the aberrant behavior of cancer cells. The CB scientific goal is to support KUCC's strategic plan by discerning the molecular mechanisms that define normal and neoplastic cell growth to identify and characterize cells, molecules, pathways, and processes that are involved in tumor growth and progression, which can serve as useful biomarkers or as new cellular targets for cancer prevention and therapeutics, particularly in tumors important to the KUCC's catchment area. To accomplish this, CB aims to catalyze collaborations that promote basic discoveries that can be translated from bench-to-bedside. CB has 46 full and 14 associate members representing four campuses: the University of Kansas Medical Center (KUMC) (67%), University of Kansas – Lawrence (KU-L) (10%), Children's Mercy (CM) (5%), and Stowers Institute for Medical Research (Stowers) (18%). In 2020, CB garnered over $9M in cancer-related, peer-reviewed funding of which $1.2M was from NCI and $6.9M was from other institutes at NIH. From 2016- 2020, members published 880 cancer-relevant, peer-reviewed papers. Of these publications, 13% were in high-impact journals (JIF >10) and the average impact factor for all 880 publications is 6.1. Since renewing the CCSG in 2017, CB program cohesion and integration have increased, with 21% of the publications during the funding cycle resulting from inter-programmatic interactions (up from 20% in 2016) and 29% from intraprogrammatic interactions (up from 21% in 2016). CB members are well-integrated into the national and international scientific community as evident by over half of the publications (51%) including authors from other institutions and 23% including authors from other NCI-designated cancer centers. CB is jointly led by Kristi Neufeld (KU-L), Linheng Li (Stowers), Sufi Thomas (KUMC), and Tomoo Iwakuma (CM), who bring complementary scientific expertise in cell biology, stem cell biology, biochemistry, translational research, leadership experience, and diverse institutional representation. Shrikant Anant is Associate Director for Basic Science. CB leadership employs a variety of mechanisms to foster intra- and inter-programmatic collaborations, including research retreats, seminars, research symposia, and targeted pilot funding. CB has taken advantage of historical institutional strengths in catchment area priorities, GI, and hematologic cancers, with recruitment strengthening our research on breast and tobacco-related cancers. CB members have expertise that can be organized into four discipline-based themes: 1) cancer metastasis and tumor microenvironment; 2) DNA damage/repair and regulation; 3) stem cell biology; and 4) cell signaling pathways.

CRITIQUE: The Cancer Biology (CB) Program is a basic science program focused on discerning molecular mechanisms of cancer to identify those that can be applied to drug and biomarker development. Efforts include pilot grants, member meetings, focused symposia, a yearly retreat. The research includes cancer types relevant to the catchment area and is focused on themes: cancer metastases and tumor microenvironment, DNA damage/repair and regulation, stem cells and treatment resistance, and cell signaling.

The 59 members (*46 full, 14 associate*) are from KUMC, KU-Lawrence, CM and Stowers. Membership has remained steady, but total funding has decreased from the last. In the previous review, there was a concern about the low level of NCI funding, which has now only moderately increased from about 11.8% to about 13.79%. Currently, the CB Program has $10.2 million in peer-reviewed grant funding with $1.4 million from the NCI. Despite some clarification during the site visit, 100% cancer-focus of some of the grants is not convincing. Efforts to increase the percentage of NCI funding have included official mentoring and peer-critiquing of grant ideas and grant application, however only one new R21 grant appears to be a product of these efforts. A greater focused effort is needed for the basic science discoveries in CB to have impact on cancer prevention, control and treatment. The Research Achievement Award recognizing CB members with high-impact factor cancer-related publications is an innovative idea for encouraging and stimulating in-depth investigations; other incentives of this type may be helpful. In the current funding cycle, they published 878 articles 13% of which were in high impact journals (≥10 impact factor), 22% inter-programmatic and 28% intra-programmatic. The total number and percentage of high impact publications has increased in the current funding cycle.

In response to low collaboration with the population science program, efforts include attendance of CB members at CPC seminars, external CPC-expert speakers, collaborations between CB and CPC members, targeted retreats, and pilot RFAs. Although the products of these efforts were not apparent in the written grant application, the CPC program presentation of clinical trials that arose out of collaboration with CB was apparent. However, the CCSG pilot and these additional collaborative efforts have not yet yielded new extramural funding and inter-programmatic publications. The previous concern over the cancer-focus of polycystic kidney disease research was addressed by transitioning the research into co-sponsored liver and kidney cancer pilot funding to members and a clinical trial of Tolvaptan in kidney cancer.

Research models used by members of the program to study CB span from yeast through fly and worm to mice. Significant research findings with high potential for translation were generated by the program members in the current funding cycle including identifying tumor microenvironment, mitochondrial and oncogenic factors that affect tumor behavior. These have focused on catchment area priorities including breast and liver cancers. It appears that this program has contributed to the translation of drugs, including repurposing atorvastatin to inhibit heat shock protein protection of mutant p53 from degradation. However, it was not clear how the CB program contributed to development of the other clinical trials based on the written application. There was a perceived disconnect between the presented vignettes and the table on page 1125 presenting the Drug discovery pipeline.

The CB Program is supported by KUCC shared resources, which have contributed to many of the new discoveries. KUCC also has provided significant pilot funding to CB Program Members that have resulted in new extramural funding. Furthermore, KUCC has leveraged resources for the recruitment of six new recruits. However, the number of CB members has been constant compared to the last submission. Both pilot funding programs and strategic funding have not increased the number of NCI awards for CB members.

Future plans are address major critiques such as modest NCI funding, lack of multi-project grants such as program project (P01) or Specialized Program of Research (SPORE) and continuing to increase transdisciplinary collaboration projects between CB and CPC and COE. Furthermore, it is proposed to elevate and energize basic research for NCI funding by targeted pilots and by providing research achievement awards for higher impact pubs. Strategic hiring in Cancer epigenetics, Immunology, and Cancer Genetics. Furthermore, the newly built CMRI provides further opportunities to grow cancer

research across the consortium. Finally, there will be increased efforts to support P01 grant application submissions and a grant review committee for extramural grants with the goal to booster success rate. All these efforts should help to regrow cancer-focused funding for this program.

Program Leader(s): With the reorganization of the programs, the previous two program leaders, Dr. Kristi Neufeld (KU-L) and Dr. Linheng Li (Stowers) were joined by Dr. Tomoo Iwakuma (CM) and Dr. Sufi Thomas (KUMC). This team represents each of the four collaborating institutions ad has clearly defined roles and areas of CB expertise that match the four programmatic themes (Table 3). Although the recommendation to include a clinician scientist in the leadership was not completely addressed, Dr. Thomas provides expertise in translational research and facilitates the connections of program members with clinicians. Dr. Kristi Neufeld, the Frank B. Tyler Professor of Cancer Research, serves as Chair lead and is located at KU-Lawrence where five CB members are located. Dr. Neufeld's research is focused on APC mutations in colon cancer development. She serves as co-investigator for a COE P30 supplement but is not currently funded for her laboratory research. Dr. Linheng Li, is a Senior Investigator at Stowers. His research is focused on hematopoietic and intestinal stem cell compartments. His research is supported by a NIDDK U01 focused on stem cells in intestinal disorders and diabetes. Dr. Tomoo Iwakuma is a Professor Pediatrics and the Director of Translational Laboratory Oncology Research at CM. His research focuses on the role of p53 pathway inhibition in cancer progression in liver and head and neck cancer. He is currently supported by an NCI R01 grant. Finally, Dr. Sufi Thomas, Associate Professor of Otolaryngology at KUMC, is also member of the Department of Cancer Biology. She studies tumor microenvironment in squamous head and neck cancer and is supported by an NCI R01 grant. A table is provided that lists a large number of tasks that are complementary but distinct for each program Co-leader, who each also represent one of the four previously mentioned CB program themes. Co-leaders also have meetings with AD for Basic Sciences to jointly build the CB program research priorities.

In summary, the CB program has produced significant potentially translatable cancer biology discoveries and increased total and high impact publications despite a decrease in funding. Some of the important accomplishments of the program members include identifying tumor microenvironment, mitochondrial and oncogenic factors that affect tumor behavior and contributing to the development of clinical trials being conducted in the D3ET and CPC programs. The program members have good utilization of shared resources and pilot funding opportunities, and their research focusses on catchment are needs, which demonstrates mutual benefit between the cancer center and the program. Low percentage of cancer-relevant funding remains since the previous review. There appears to be missed opportunities for enhanced collaboration with the other two programs. Future plans are appropriate for addressing their low level of multi-project and NCI-specific funding, and research interactions with CPC and D3ET Programs.

Budget. Each program leader has 10% effort. Only the Program Lead Dr. Neufeld has effort on this grant, while the others have their efforts funded elsewhere. Appropriate.

Assessment: Outstanding to Excellent merit.

Budget: The budget is appropriate as requested.

Cancer Prevention and Control Program

DESCRIPTION (provided by applicant): The Cancer Prevention and Control (CPC) research program at The University of Kansas Cancer Center (KUCC) brings together an interdisciplinary team of researchers focused on: 1) developing, testing, and implementing innovative strategies to modify behaviors that drive cancer risk and disparities in cancer incidence (Population-Level Primary Prevention); 2) identifying biomarker-driven opportunities for cancer prevention among high-risk individuals with premalignant disease or hereditary cancer risk and testing interventions to improve detection and modulation of risk biomarkers associated with cancer prevention in these high-risk patients (High-Risk Prevention); and 3) developing and disseminating behavioral, nutritional, and clinical support interventions to address the impact of cancer (Survivorship). The 49 members of CPC come from 23 departments in six schools. They represent a rich mix of expertise, including behavioral science, neuroscience, primary care, nursing, oncology, epidemiology, economics, translational biology, pharmacology, communications, biostatistics, and health services research. Program members are supported by $13.3M in total annual funds, including $3.8M from the National Cancer Institute. Currently, 69% of CPC members are principal investigators on externally funded cancer research grants. CPC program activities support both intra and inter-programmatic interactions through translational research seminars, a visiting scholar program, and cancer care delivery and equity, tobacco control, implementation science, and health services research working groups. These activities have fostered intra- and inter-programmatic productivity, resulting in 225 articles published by CPC members in 2020, of which 20% had inter-programmatic, 32% had intraprogrammatic, and 67% had external collaborations. The work in CPC begins and ends with the needs of the KUCC catchment area. CPC members have shown remarkable success in developing the infrastructure to conduct cancer prevention and control research in our region among rural, African American, Hispanic, and American Indian communities and individuals in the criminal justice system. A strong mentorship program places a significant focus on training. Seven CPC trainees received more than $1.2M in extramural training grant support in 2020 alone; CPC members have demonstrated a 9.2-fold return from CCSG Developmental Funds and a 23.3-fold return from KUCC Pilot Projects. The shared work of CPC members has led to: a better understanding of the cancer control needs in the KUCC catchment area; improved capacity to analyze the needs of affected and at-risk populations; identification of novel pre-cancerous models and new biomarkers; improved strategies to detect and prevent cancer in high-risk patients; better strategies for the design and delivery of cancer prevention and control messages; and improved delivery of tobacco control, cancer screening, physical activity, obesity, and survivorship programs at the level of both the clinical practice and the community-at-large.

CRITIQUE: The mission of CPC is to reduce cancer burden and cancer disparities with attention to the top cancer priorities within the KUCC catchment area. There are three goals of the Cancer Prevention and Control program: 1) to advance primary-level population prevention, 2) to improve high risk prevention, and 3) to address survivorship needs of patients from diagnosis and for the balance of life.

The Cancer Prevention and Control Program consists of 58 members from 23 departments in six schools. This is a restructured program from a merger of previous Cancer Control and Population Health and Cancer Prevention and Survivorship Programs, in response to the previous review. The process by which the leadership reviewed the critiques and planned for the new program is well explained in the application.

The total peer reviewed funding is $12.5 million of $3.9 million is from the NCI. It would seem that the majority of the members from the two former programs are a part of the newly formed program, yet

funding appears to be lower per member. Overall, in CY 2021 CPC members held 61 grants with research funds totaling $14 million. Mentoring junior faculty and students is a priority, evident by the opportunities made available through CPC. In addition, five junior faculty CPC members were funded on career development awards. CPC members are conducting research that directly impacts the KUCC catchment area as illustrated by accrual into both intervention and non-interventional trials (n=7897 over five years) from communities across Kansas and Western Missouri. Trials currently being conducted target breast, colon, prostate, and lung cancer survivors, pediatric cancer survivors, and groups at high risk for cancer due to lifestyle practices or high-risk conditions (e.g., Lynch syndrome, colorectal polyps), among other things.

The CPC program reports an impressive 274 publications in 2021 alone. Of these 9% were in journals with an impact factor of 10 or higher, and 18%, 31%, and 66% were inter-programmatic, intra-programmatic, and included external collaborations, respectively.

Weaknesses identified in the previous review have been adequately addressed. The CPC Program has incorporated metabolic and genetic markers of treatment success in both tobacco control and obesity cancer-related research and expanded other biomarker work through collaborations with shared resources programs in clinical pharmacology (CPSR) and nutrition (NSR). Notably, 78% of CPC members reported using a KUCC shared resource in 2020 – 27% used Clinical Pharmacology. The CPC recruited two investigators with expertise in epigenetics and genetics and has made efforts to integrate genetics into cancer prevention and control projects and is acting to incorporate genetic risk assessment into clinical practice survivorship care. Further, the reorganization has facilitated interactions with Cancer Biology and Drug Discovery, Delivery and Experimental Therapeutics Programs. The current application describes a number of new intra-programmatic partnerships with joint seminars and shared pilot-grant funding to encourage new and expanding collaborations. It was not clear how many clinicians are part of CPC; however, there seem to be a number of primary prevention trials being conducted in clinical settings within the catchment area.

The strong programs in tobacco control and in obesity noted in the previous review have continued their trajectories of success and involve many CPC researchers in inter-programmatic projects. KUCC researchers have conducted tobacco cessation and treatment research that has been informed by community advisory boards and other community groups and in partnership with Swope Health Central, a large Federally Qualified Health Center in western Missouri. This work has informed clinical practice for treating African American light and non-daily smokers and has been instrumental in understanding the lower rates of quitting among African American smokers. An ongoing randomized clinical trial lead by CPC investigators, Drs. Ellerbeck, Catley and Cox, will test a text-messaging cessation intervention among a different population, Latino smokers in rural southwest Kansas. In addition, CPC researchers have influenced public policy through their tobacco research with young people, likely contributing to the Kansas City region becoming an early adopter of Tobacco 21 (T21) laws (increasing the age of sale for tobacco products from 18 to 21 yrs.). Taken together, scientific findings and from this area of research have important public health implications.

In 2020, over 60% adults in Kansas were overweight or obese. Consistent evidence indicates that energy imbalance and excess body weight are associated with increased risk of at least 13 types of cancer, among them colorectal, esophageal, liver, pancreatic, gallbladder, postmenopausal breast, uterine, and ovarian cancers; thus, overweight/obesity are important cancer prevention and control problems for the catchment area. CPC researchers have led successful projects that address obesity and cancer prevention and control in primary care practices and community settings which have been

published in high impact journals and have been widely disseminated. Recent results from a large cluster randomized weight loss trial were published in JAMA (2020). Subsequent research conducted through the Cooperative Extensive Service evaluated the role of telehealth in weight maintenance and was published in Annals of Family Medicine (2020). This work was featured in a 2021 Society of Behavioral Medicine policy brief for obesity treatment for isolated rural communities and informed a National Academies policy workshop focused on weight management throughout the cancer continuum. Physical inactivity and sedentary behaviors are important contributors to weight management and to cancer risk. Several awards to Carlson and co-investigators target physical activity and sedentary behaviors using novel measurement strategies such as video analysis and Global Positioning Systems (GPS) to capture and characterize these lifestyle behaviors in public settings and link them to cancer-related risk factors such as body fatness and insulin resistance. Drs. Donnelly, Washburn, and Ptomey are studying different methods for delivery of physical activity interventions targeting youth.

The KUCC CPC investigators are also conducting innovative cervical cancer prevention research in criminal justice settings. Dr. Ramaswamy and colleagues are among the few groups in the country addressing cancer disparities among women in prisons and jails. Ramaswamy leveraged two CPC pilot awards and has obtained three NCI-funded R01 grants in support of HPV vaccination and cervical cancer prevention projects. Additionally, two junior faculty have been awarded related diversity supplements. Future plans in this area include a P01 grant application submission.

KUCC researchers have also made significant contributions in the survivorship realm. The CPC investigators have conducted successfully weight loss trials among rural breast cancer survivors and among prostate cancer patients prior to prostatectomy surgery and were supported in these efforts by shared resources in biostatistics and nutrition. Both of these studies evaluated both weight loss and weight loss maintenance as endpoints. Other multi-investigator survivorship research has assessed treatment-related effects, late effects (e.g., muscle wasting, sarcopenia, infections, cognitive function) and patient-reported outcomes among patients with many types of cancer (e.g., breast, colorectal, lung, prostate). This line of research has featured qualitative methods, observational research and the delivery of targeted interventions to improve quality of life and reduce cancer burden.

The KUCC has added value to CPC. Approximately 78% of CPC members made use of shared resources. Over the past five years CPC members have been benefitted from 45 pilot awards totaling over $1.8 million, which they have parlayed to obtain $10.9 million in extramural funding (~6-fold return on investment). In addition, KUCC has contributed to recruitment efforts to meet program needs in radiation oncology, patient-oriented health services research, pharmacoepidemiology, genetic epidemiology, cancer prevention and control in high-risk patients and metabolism and cancer.

CPC, like the CCPH program from which it arose, shows continued commitment of the center to maintain a significant presence in multiple underserved populations in the catchment area, including women who have been incarcerated, rural primary care patients, and racial and ethnic minorities. There is significant investigator effort to develop specific trials to address the needs of these unique populations, addressing a prior critique.

Program Leader(s): Dr. Edward Ellerbeck is a board-certified internist with 35 years of clinical experience and a long and successful career of research focused on improving medical care. He served as chair of the department of Population Health for 14 years and he co-led the former CCPH program from 2012-2019. He Directs the KL2 training program for the CTSA. Appropriately, given this

background, his role in the Cancer Prevention and Control program leadership focuses on career development and development of pragmatic cancer control efforts in rural and underserved primary care settings. Dr. Ellerbeck will have primary responsibility for overseeing pilot grant activities, recruitment and onboarding of new members, oversight of student programs, abstract solicitation and reviews at the annual meeting, and interactions with training efforts to support member development. Dr. Ellerbeck's research career has included methodologic work in health services, smoking cessation, infrastructure to promote pragmatic trials in rural primary care (KPPEPR). His is a long-term successful leader for this program.

Dr. Jennifer Klemp is a clinical health psychologist, Professor of Internal Medicine. She co-led the CPS program from 2016-2019 and joined the CPC leadership team when the program was formed in 2019. Her role in the leadership of the Cancer Prevention and Control program is to facilitate and develop clinical research across the cancer control continuum across the institution, its partners, and the catchment area. Dr. Klemp's primary responsibilities will be overseeing the monthly seminar series, coordination of efforts with the Protocol Review and Monitoring Committee, planning for program retreats and the annual scientific meeting, and working to bring in outside speakers. Her clinical practice focuses on cancer genetics, and her research focuses on primary and secondary cancer prevention, outcomes, and translation of this work into community based and rural practice locations. Her current ongoing NCI funded R01 grant uses the Project ECHO framework to increase evidence-based care for rural cancer survivors. She is the founder and CEO of a company that aims to improve survivorship care in ways that empower healthcare systems to provide evidence-based care to patients. She is a national leader in cancer genetics and survivorship care, including roles on the Academy of Oncology Nurse and Patient Navigator Leadership Council.

Dr. Nicole Nollen holds a PhD in Counseling Psychology and is a Professor in the Department of Population Health. Her role in the leadership of the Cancer Prevention and Control program is primary responsibility for overseeing all NH, EAB, and other reporting activities, including progress reports, planning, presentations, and the CCSG renewal application. Her research focuses on understanding determinants of health and health behaviors among vulnerable populations. She has focused much of her work on nicotine addiction treatments, as well as mechanisms underlying tobacco use and treatment outcomes. Her current funding includes a NIDA R01 grant to increase smoking cessation in the African American Community.

Dr. Christie Befort, Associate Director, is a Professor in the Department of Population Health. She was co-leader of the former CCPH program. She oversees recruitment for the program and coordinates efforts to ensure a range of expertise in population sciences to address the broad spectrum of topics covered by the program aims. She oversees the interface between the program and the Community Outreach and Engagement team, toward the goal of ensuring the research of the CPC program is pragmatic and relevant to the catchment area, with a particular focus on the rural catchment. She is an active mentor to junior faculty, post docs, and predoctoral trainees. Dr. Befort's research program has significant strengths in obesity treatment in rural primary care, including a recently completed large pragmatic trial funded by PCORI. She also has performed research on weight control in breast cancer survivors, weight loss intervention delivery strategies for underserved populations, and factors associated with adherence ad response to lifestyle intervention.

Overall, the science of this program is strong, diverse, and deeply addresses the catchment area. The aims (themes) of the program members are primary prevention, prevention in high-risk populations, and survivorship. Some of the important accomplishments of the program members include the breadth,

depth and transdisciplinary research, strong training, and compelling involvement in the catchment area. The program has a strong publication record. The program activities are appropriately divided across sites at this consortium center. The use of patient advocates to inform the research relevant to the catchment area is exceptional. The program is a frequent user of the shared resources and participates heavily in all training activities of the center. The program is also appropriately outward facing, influencing policy in the catchment area and addressing underserved populations. There is an opportunity for inter-programmatic projects with external funding.

Assessment: Exceptional merit

Budget: The budget is appropriate as requested.

Drug Discovery, Delivery and Experimental Therapeutics Program

DESCRIPTION (provided by applicant): The Drug Discovery, Delivery and Experimental Therapeutics (D3ET) research program integrates a broad range of research areas that contribute to the discovery of new cancer therapeutic agents as well as novel approaches to effective drug delivery; the development of drug products and diagnostics for the treatment and prevention of cancer; and the evaluation of these medical innovations in hypothesis-driven experimental therapeutics trials. D3ET is organized around three central, highly integrated scientific themes: 1) Drug Discovery and Delivery; 2) Drug and Diagnostic Development; and 3) Evaluation of New Cancer Treatment Strategies in Experimental Therapeutic Trials. D3ET has 62 members, including 36 full and 26 associate members. Membership reflects a range of senior and early stage investigators with 27 Professors, 13 Associate Professors and 20 Assistant Professors and two key shared resource personnel. D3ET members are drawn from 25 departments across Children's Mercy (CM), the University of Kansas in Lawrence (KU-L), and the University of Kansas Medical Center in Kansas City (KUMC), providing a rich environment for discipline diversity and team science. During the reporting period (CY20), 85% of program members have cancer relevant, externally funded research grants. From 2016-2020, the D3ET program achieved a strong and growing cancer-focused research portfolio. D3ET members have doubled funding (increase of $15M) over the past five years with $7M of this increase comprised of peer-reviewed funding and $8M of non-peer reviewed funding, along with a near doubling of NCI-sponsored direct funding. D3ET has successfully advanced five KU-invented cancer therapeutic agents (See Table 4), to clinical trials over the past four years. The D3ET program has made substantial progress in publishing its research and increasing intra-programmatic (33%) and interprogrammatic (21%) collaborations. Between 2016 and 2020, D3ET members published 902 cancer-relevant publications (an average of 14.5 publications per member), including 142 high-impact publications in journals with impact factors ≥ 10.0 (16%). D3ET is jointly led by John A. Taylor, MD, MS (KUMC), Priyanka Sharma, MD (KUMC), and Dan A. Dixon, PhD (KU-L), who bring complementary scientific expertise in drug discovery, development and experimental therapeutics and strong track records of mentorship. This highly interactive leadership team meets biweekly with Scott Weir, PharmD, PhD (KUMC), Associate Director for Translational Research, to ensure seamless integration with broader cancer center goals and initiatives.

CRITIQUE: The Drug Discovery, Delivery and Experimental Therapeutics (D3ET) research program was rated outstanding. This program is led by Drs. Priyanka Sharma, John Taylor, and Dan A. Dixon. The program has approximately $9.9 million (direct) in peer-reviewed funding, with approximately 4.8 million from the NCI, representing a strong funding growth. The program is organized into scientific themes: 1) Drug Discovery and Delivery; 2) Drug and Diagnostic Development; and 3) Evaluation of New Cancer Treatment Strategies in Experimental Therapeutic Trials. Some of the important

accomplishments of the program members include advancement of three KU-invented small-molecule drugs and two cell-based therapies into clinical development. There are significant increases in investigator-initiated clinical trials. The program has a strong publication record, with 902 publications in total with 33% of intra-programmatic publications and 21% of inter-programmatic publications and 142 of which are in high-impact journals. This program also has a strong pipeline and demonstrates extensive collaborations with the Cancer Biology program.

The three themes of this program are focused on: 1) Discovery and Delivery; 2) Drug and Diagnostic Development; and 3) Evaluation of New Cancer Treatment Strategies in Experimental Therapeutic Trials. They are similar to the prior cycle with the exception of including diagnostics in development. This latter point is viewed favorably and reflects a precision medicine focus and the evolution of the field.

The program has 62 members of whom 36 are full members (58%). Membership includes a healthy and robust mix of individuals inclusive of basic scientists, translational and clinical investigators. This is viewed as an important asset and provides the type of rich environment necessary for a program with the objectives translating drug discovery research into investigator-initiated clinical trials. Members are drawn from KU-L, KUMC, and CM.

Dr. Priyanka Sharma, who is a breast cancer medical oncologist. Dr. Sharma serves as Vice Chair SWOG Breast Cancer Committee and leads several funded efforts and trials through SWOG and leads breast cancer disease working group. Dr. Dan Dixon is a basic scientist and Professor of Molecular Bioscience. Dr. Dixon was previously co-leader of the Cancer Prevention and Survivorship Program. Third co-leader is Dr. John Taylor (MD), who is Professor of Urology and is a funded investigator in bladder cancer pre-clinical modeling and drug development. Dr. Taylor helped develop the KUCC developed drug fosciclopirox for treatment of bladder cancer and co-chairs the D3SC steering committee. All of these three co-leaders are funded investigators, have complementary skillsets in the stewardship of the program and are well qualified to co-lead this program. There appears to have a nice delineation of the roles of each of the co-leaders based on expertise.

This program demonstrates a marked improvement in key metrics, with 85% of members having cancer-relevant external funding. The program members have received a total funding of $24.9 million for 2021, with $12.8 million peer-reviewed funding and $4.8 million peer-reviewed NCI funding, representing a strong growth over the previous funding period. Over the current cycle, three KU-invented small-molecule drugs and two cell therapies have been advanced into human clinical trials. The D3ET program is driving the vast majority of recruitment to therapeutic clinical trials. These are inherently difficult metrics, and their combined improvement is a testament to the strength of this program. The program has a strong publication record, with 902 publications in total with 33% of intra-programmatic publications and 21% of inter-programmatic publications and 142 of which are in high-impact journals (IF > 10).

This program provides a strong example of the positive effects of alignment of leadership, in this case with the three D3ET program leaders and the AD for Translational Research. It has created an environment of collaboration, based on a team-based approach, integrating KUCC research programs, other NCI-designated cancer centers and academic institutions, and the private sector.

D3ET has been well integrated with other programs, with 16 of 28 targets being investigated coming from the Cancer Biology Program, and membership in NCORP, CATCH-UP and COG PEP-ECTN providing mechanisms to reach underserved rural populations.

The Drug Discovery and Development Steering Committee (D3SC) is the engine that underlies D3ET operations and success. It represents an innovative approach. Coupled to Disease Working Groups, of which there are 16, and the operations of the Clinical Trials Office, these committees provide for a highly efficient operation. The discovery and development of CPX-POM is provided as a case-study and highlights many metrics of scientific and operational success. Programmatic work in small extracellular vesicles and cell free DNA represent cutting edge technologies poised to fundamentally advance the field.

D3ET creatively engages in COE activities, giving patients voices through its PIVOT program, and fosters transdisciplinary collaboration through public-private partnerships. High levels of bidirectional value added are evident. There has been good use of the shared resources with greatest utilization by members of the biospecimen, biostatistical& informatics, clinical pharmacology, and lead development and optimization shared resources.

Good demonstration of a robust series of program meetings throughout the funding period, there is also a clear program steering committee appearing to meet monthly. This is complemented by an investigator-initiated trial steering committee. There is also good demonstration of inter-programmatic meetings and transdisciplinary committee meetings.

Program Leader(s): The Drug Discovery, Delivery and Experimental Therapeutics (D3ET) research program was rated outstanding. This program is led by Drs. Priyanka Sharma, John Taylor, and Dan A. Dixon. The program has approximately $9.9 million (direct) in peer-reviewed funding, with approximately 4.8 million from the NCI, representing a strong funding growth. The program is organized into scientific themes: 1) Drug Discovery and Delivery; 2) Drug and Diagnostic Development; and 3) Evaluation of New Cancer Treatment Strategies in Experimental Therapeutic Trials. Some of the important accomplishments of the program members include advancement of three KU-invented small-molecule drugs and two cell-based therapies into clinical development. There are significant increases in investigator-initiated clinical trials. The program has a strong publication record, with 902 publications in total with 33% of intra-programmatic publications and 21% of inter-programmatic publications and 142 of which are in high-impact journals. This program also has a strong pipeline and demonstrates extensive collaborations with the Cancer Biology program.

Overall, this program has achieved remarkable growth and success, has done so in the historically difficult and inefficient areas of drug discovery and development, and has done so in a manner to meets and propels many of the central thematic elements of a cancer center. Important goals will be to maintain this remarkable momentum, and to enhance opportunities for education.

Assessment: Outstanding merit

Budget: The budget is appropriate as requested.

SHARED RESOURCE MANAGEMENT

DESCRIPTION (provided by applicant): Shared resources play a critical role in enhancing and supporting the scientific, outreach, and educational endeavors of The University of Kansas Cancer Center (KUCC) and its 171 members. A proposed shared resource is given consideration for official KUCC Cancer Center Support Grant (CCSG) shared resource status based on the number of members served as well as the depth and breadth of science enhanced. KUCC continually assesses its shared resources to ensure they have distinct services to avoid overlap of support, have a solid user base of KUCC membership utilizing the resource, are cost-effective, have systems to track utilization, are accessible to all members across our four campuses, and have charge-back rates that have been approved by institutional finance and meet the NIH guidelines. All shared resources adhere to the following prioritization for providing support: 1) KUCC members with NCI grants or applying for NCI grants and KUCC pilots; 2) KUCC members with cancer or cancer-related grants funded by other NIH institutes or other peer-reviewed grants as defined by the NCI or applying for such grants; 3) KUCC-sponsored non peer reviewed projects; 4) Other grants or contracts that are not peer-reviewed (e.g., philanthropy or industry funded); and 5) Unfunded projects. These priorities place the highest emphasis on peer-reviewed funded research projects as a means of assuring that support is provided to high-quality research. Continual feedback has been ascertained using surveys, focus groups, individual member input, external experts, and assessment and guidance by KUCC leadership. The annual shared resource survey in 2020 showed 94-100% satisfaction for all shared resources. A key focus during the previous grant cycle has been to enhance shared resource access across all four campuses as well as stimulating more use across membership and the utilization of multiple shared resources. Member usage spans all research programs and campuses and has grown considerably from 99 in 2010, to 113 in 2015 and now 137 in 2020. KUCC also tracks super users, members who utilize three or more shared resources within a year. The number of super users has grown from nine in 2010, to 23 in 2015, to now 52 in 2020. Since our initial application, usage has increased across all three programs: Cancer Biology has gone from 41% of members utilizing shared resources to now 78% of members utilizing shared resources; Cancer Prevention and Control has gone from 69% of members utilizing shared resources to now 78% of members utilizing shared resources; and Drug Discovery, Development and Experimental Therapeutics has gone from 54% of members utilizing shared resources to now 84% utilizing shared resources. In 2019, KUCC undertook a strategic planning effort to identify enhancements for shared resources to meet the ever-changing needs of members over the next five years. These enhancements totaled over $5M in requests and initial investments have already begun with an expected outlay of additional support of over $1M in 2021

CRITIQUE: KUCC proposes seven full and one developing shared resource, which are located on the various campuses according to their utilization needs. The majority are located on KUMC campus and two are located at KU-L. In 2020, there was a high 80% usage of the shared resources by cancer center members. Usage has increased across all four institutions and three programs. There are appropriate means of surveying cancer center members for needs and competencies of shared resources. A well-thought-out strategy involving designated EAB members and IAB/EABs for each shared resource in the decision-m-king process is described. There appears to be a relatively robust assessment mechanism provided through surveys to the membership, which has led to the continued support of certain shared resources or, importantly, withdrawal of support for underperforming or underutilized shared resources. In the current funding period, a decision was made to no longer support two developing shared resources (cell line authentication and health communications) and instead develop a new shared resource in microscopy and analytical imaging. The resources include vital support needed for general cancer research in the form of tissue banking, biostatistics, flow cytometry

and microscopic imaging. Other resources that meet the specific focus of this cancer center are related to drug discovery/development and nutrition. The choice to develop a Microscopy and Analytical Imaging Shared Resource (MAISR) is based on needs of at least two productive members, Drs. Thomas and Godwin, for which this resource developed a 2-photon-based technological approach to evaluate roles of specific proteins in invadopodia and extracellular vesicles in cancer metastases, respectively. Only a small percentage of the budget is funded by the CCSG. Information on the cost-benefit to the cancer center members was not provided in shared resources management writeup and comparisons of the shared resource costs to the investigators compared to the costs at other institutions was inconsistently described within each of the cores.

A weakness is that the oversight of each shared resource is described in a relatively cursory fashion. It is noted that each shared resource has an internal advisory board, and some utilize additional external advisory boards, yet this is not described in any detail in the grant application. This was partially explained at the site visit in terms of how often the internal advisory boards meet; however, it was still not entirely clear how the input is utilized from these advisory boards to institute improvements. There was considerable verbiage in the grant application regarding individual shared resources and individual shared resource leadership critiques from the previous review. However, more attention describing the mechanisms in place to ensure accessibility and quality of these various shared resources across multiple campuses and consortia partners would have been helpful.

Leadership: Dr. Mayo has appropriate experience in academic leadership and in directing biostatistical shared resources for the cancer center and CTSA, which he is applying to directing all of the shared resources in this cancer center. His commitment of 20% effort to shared resource management is a strength. Dr. Lisa Harlan-Williams is the Assistant Director for Administration and Education and provides administrative support for Dr. Mayo and the shared resources. Dr. Harlan-Williams gathers progress reports and usage data annually and facilitates the development of annual poster presentations to the KUCC external advisory board. Each shared resource has at least one director and some have two co-directors with appropriate qualifications. Dr. Mayo provides oversight and administrative leadership for each shared resource and meets with the directors quarterly and on an as-needed basis to identify appropriate utilization metrics and tracking mechanisms. In addition, Dr. Mayo coordinates an annual member survey or focus group to align services with member needs and improve effectiveness, quality, and satisfaction services. Overall, these processes seem relatively standard and established.

Assessment: Excellent to Outstanding merit

Budget: The budget is appropriate as requested.

SHARED RESOURCES

Biospecimen Shared Resource

DESCRIPTION (provided by applicant): The Biospecimen Shared Resource (BSR), led by Andrew K. Godwin, PhD (Founding Director, BSR; Deputy Director, KUCC, and D3ET member), and by Rashna Madan, MBBS, FCAP, FASCP (Assistant Director, BSR), plays a vital role in The University of Kansas Cancer Center (KUCC) by its ethical collection, storage, annotation, and distribution of high-quality human biospecimens, such as fresh/fresh-frozen tumor tissues of varying histology and bodily fluids (e.g., blood, bone marrow, saliva, urine, ascites fluids), which are essential to support translational

research and investigator-initiated studies. The BSR also provides expert histopathology support and combines the expertise of pathologists, translational researchers, and technical personnel to produce a comprehensive and focused approach to support the research activities at KUCC. The BSR, rated "exceptional to outstanding" in 2017, continues to evolve to meet the ever-expanding and diverse needs of our KUCC members for highly annotated clinical samples. Additionally, tissue biospecimen collection is facilitated by pathology assistants, residents and fellows at the KU Hospital and the Indian Creek Campus (ICC) as part of The University of Kansas Health System's (TUKHS) commitment to the BSR. The BSR is fully equipped for biospecimen collection, processing, and distribution, and thus, the BSR adheres to the OSHA laboratory standards for handling cryogens, ISBER Best Practice for Repositories, and NCI Best Practices for Biospecimen Resources, and has developed Standard Operating Procedures to govern each of these processes. The collection, processing, and distribution of specimens by the BSR staff has grown substantially over the funding period and now includes collections of pediatric specimens from ICC and Children's Mercy (CM) and underserved populations from the satellite biospecimen bank at Truman Medical Center (TMC), a member of the Masonic Cancer Alliance (MCA) and the largest safety-net provider in the Kansas City Metropolitan area. Since founding the CCSG BSR in 2011, we have enrolled 51,916 consented individuals and supported the banking of 4,795 participants for investigator-initiated studies resulting in regular usage of deidentified biospecimens and matching clinical data. During the current grant cycle (2016-2020), the BSR provided key services in support of 150 publications (57 papers ≥ 10 impact factor), 96 unique cancer center members, and >35 NIH/NIGMS/NCI grants and contracts including, 1 K01, 1 R00, 12 R01s, 1 R03, 6 R21s, 1 R33, 1 R35, 2 R43, 2 P20, 1 P30, 1 P41, 2 U01, TCGA 13XS194, & CPTAC 14X215, 16x257, 19x139 and 311 clinical trials. In the reporting year (2020), the BRS supported 82 different users (54 KUCC members across all three programs, of which 85% were funded and 28 non-members, including 16 cancer-focused researchers nationally). The proposed budget of the BSR (year 11) is $1,511,949, yet the CCSG request is $118,342. As such, the BSR leverages grants, contracts, user fees, and extensive institutional support and seeks only 7.8% support from CCSG funds

CRITIQUE: The Biospecimen Shared Resource (BSR) is a long-standing and essential resource for the Cancer Center. It was well received in the previous review and continues its strong support of the KUCC mission, supporting all three programs. Key services include centralized and uniform procedures for collection, processing, and storage of biospecimens, including support for investigator-initiated clinical trials and specialized biobanks, and histology and pathology support.

The number of biospecimens collected and distributed and number of investigators using the BSR continues to grow with each funding cycle, with support for more than 300 clinical protocols and 200 projects with >35,500 samples in the last funding period (nearly 52,000 since founding of the CCSG BSR in 2011). Use by KUCC investigators remains high (96 unique members across all three programs). Investigator-initiated banks supported by the BSR include specialized repositories for Triple Negative Breast Cancer, Breast DCIS, heme malignancies, and CAR-T-treated malignancies, in alignment with cancer types targeted by KUCC research programs. Banking protocols follow current best practices from ISBER and the NCI. Other services offered include state-of-the art research histology, consultation with BSR pathologists, and tissue microarray block construction.

The BSR leverages funding from several sources including the CCSG to maintain a low fee-for-service rate of 21%. In addition to maintaining a centralized bank, the BSR works with the Clinical Trials Office (CTO) and KUCC investigators to anticipate and meet the needs for tissue and blood-based diagnostics in investigator-initiated clinical trials (IITs). BSR support for IITs increased >1.5-fold over the

past 5 years and continues to be a major aim of the shared resource. The BSR also participates in several key NCI initiatives including TCGA, CPTAC and Confluence.

The BSR has undertaken several efforts to increase participation of under-represented minority populations through strategic efforts with the MCA and JUNTOS Center for Advancing Latino Health. In partnership with these organizations as well as the Truman Medical Center (TMC), the BSR has begun a project to increase engagement with underserved communities and recruitment of under-represented minority individuals through community-based biospecimen collection drives and educational outreach. Through the MCA, a community health educator has been hired to focus on biospecimen education and participation in black populations. The BSR has partnered with JUNTOS to translate consent forms into Spanish and to provide educational outreach to Hispanic communities about biorepositories. A minor weakness is that the metrics that will be used to gauge the success of outreach efforts in the future are not specified.

The BSR is directed by Andrew Godwin, PhD, founding Director of the KUCC BSR, who is also Deputy Director of KUCC, Director of the Clinical Molecular Oncology lab, and leader of the KUCC ovarian cancer program. Dr. Rashna Madan, a surgical and cytopathologist, has served as Assistant Director of the BSR since 2011 and has been instrumental in ensuring the quality of samples included in the biospecimen repository. Hematopathology expertise is contributed by Dr. Wei Cui. All are highly qualified and bring synergistic expertise (basic and translational research, diagnostic pathology) to the BSR. There are nineteen support staff, which should ensure more than adequate staffing for BSR activities.

The BSR has been highly responsive in meeting needs of KUCC investigators. In addition to customized biorepository support, the histology services are heavily used, with a 59% increase in use over the last funding period. Plans include support for a new spatial profiling system, which has the potential to increase demand for BSR services. An eConsent module directly linked to the BSR inventory system was rolled out in 2021, and the BSR will continue to work with the Curated Cancer Clinical Outcomes Database (C3OD) database development team on enhancements; this database is vitally important to translational research as it links the samples to clinical annotation. Approximately 20 annotation datasets are provided to the BSR by C3OD annually. A major aim of the BSR in the next funding cycle is to continue to support the development of a curated database of clinical information.

In summary, the BSR continues to be extremely productive and cost-effective in providing comprehensive histopathology and biorepository support to KUCC investigators. Strengths include the centralized, cost-effective investigator-tailored approach to biospecimen collection, distribution, and curation; robust and heavily used histopathology services with access to expert pathology consultants; and the strong leadership team. Future plans include continued improvements to the quality and value realized from human subject specimens obtained in clinical cancer research studies. Weaknesses include the need for documentation of metrics and benchmarks for achieving success of outreach efforts; however, these are minor and do not detract from the overall exceptional quality of the Shared Resource.

Assessment: Exceptional merit

Budget: The budget is appropriate as requested.

Biostatistics & Informatics Shared Resource

DESCRIPTION (provided by applicant): The Biostatistics and Informatics Shared Resource (BISR) plays an essential role in the research activities of The University of Kansas Cancer Center (KUCC) by supporting the data science needs of KUCC investigators. The BISR is co-led by Byron Gajewski (CPC), PhD, and Devin Koestler (CB), PhD, both accomplished biostatisticians with a long-standing commitment to cross-disciplinary collaborations. The BISR includes 19 faculty members with specialized cancer biostatistics research expertise, 13 technical support staff and postdoctoral fellows, and three administrative staff members who provide additional technical and administrative expertise, adding efficiency to the resource. The BISR assists KUCC investigators by providing guidance and direction in study design, statistical oversight and analyses, clinical research informatics and data management, electronic data collection, bioinformatics, complex data set (statistical 'omics) analysis, and investigator-initiated clinical trials. The BISR consists of faculty and staff whose diverse expertise and skill sets span the areas of biostatistics, bioinformatics, and informatics. The considerable overlap between these three areas allows researchers to work with a single shared resource for their data collection, analytics, and statistical analysis needs. The synergy between the areas that encompass "data science" enables the BISR to support a wide range of quality services in a timely and cost-effective manner. To support the research activities of KUCC members, the specific aims of this resource are to: 1) provide study design and statistical support and expertise; 2) provide bioinformatics and statistical genetics support and expertise; 3) provide informatics expertise for data collection and management, as well as develop and support ongoing research enabling technologies, platforms, and tools; and 4) educate students, fellows and faculty members of KUCC on data science, reproducible research ideas, and methods used in cancer research. From 2016-2020, the BISR supported 69, 60, 85, 80, and 78 KUCC members respectively. In 2020, the breakdown was 18, 33, and 27 members from Cancer Biology, Cancer Prevention and Control, and Drug Discovery, Delivery and Experimental Therapeutics, respectively, on 89 grant applications (submissions and resubmissions) and 161 projects (ongoing grants, IITs, and other projects). In addition, the BISR supported 31 non-member cancer researchers in 2020. For all cancer-related projects, the BISR supported 340 grant applications plus projects in 2020. In 2021, CCSG funding accounts for ~10% of the BISR budget, with an annual direct support return on investment of approximately $0.6M dollars in external funding to support BISR faculty and staff (31% of BISR support).

CRITIQUE: The Biostatistics and Informatics Shared Resource (BISR) provides expertise in study design, statistical analysis and oversight, clinical research informatics and data management, electronic data collection, bioinformatics, and statistical genomics. Specific aims of the BISR are to: (1) provide study design and statistical support and expertise; (2) provide bioinformatics and statistical genetics support and expertise; (3) provide informatics expertise for data collection and management, as well as develop and support ongoing research enabling technologies, platforms, and tools; and (4) educate students, fellows and faculty members of KUCC on data science, reproducible research ideas, and methods used in cancer research.

The shared resource is headed by Dr. Byron Gajewski, Professor in the Department of Biostatistics & Data Science, and Dr. Devin Koestler, Associate Professor in the Department of Biostatistics & Data Science, who have served in these roles since the previous renewal. BISR consists of 19 PhD level faculty, 13 technical support staff and post-doctoral scholars, three administrative staff, and about 12 GRAs. The BISR faculty and staff have expertise across a wide range of quantitative fields necessary to support the research of the University of Kansas Cancer Center (KUCC). The shared resource is organized in a hierarchy of subunits, with three at the top-level and ten at a secondary level, all linked

to support of IITs. From 2016-2020, the BISR supported 69, 60, 85, 80, and 78 KUCC members respectively. In 2020, the breakdown was 18, 33, and 27 members from Cancer Biology, Cancer Prevention and Control, and Drug Discovery, Delivery and Experimental Therapeutics, respectively, on 89 grant applications (submissions and resubmissions) and 161 projects (ongoing grants, IITs, and other projects). In addition, the BISR supported 31 non-member cancer researchers in 2020. For all cancer-related projects, the BISR supported 340 grant applications plus projects in 2020.

In response to the previous weaknesses that BISRs impact on investigator-initiated trials (IITs) and overcoming geographic barriers, the BISR has taken several steps to increase its impact on IITs over the current funding period: (1) appointment of Drs. Phadnis and Mudaranthakam to oversee IITs; (2) BISR's participation in bimonthly IIT Steering Committee Meetings; (3) service on the Executive Resource Committee (ERC); (4) recruitment of two staff-level research analysts to provide further analytical support for IITs; and (5) the development of novel tools to track and monitor IIT accrual (demonstrated in three publications). To overcome geographical barriers, the BISR has: (1) invested in technology to improve long-distance collaboration; (2) delivered regular presentations at the KUCC seminar series and the KUCC Research Symposium to raise awareness of the BISR; and (3) hired Dr. Sardiu to increase collaborations with Stowers. These efforts led to publications/grants with consortium partners.

The previous review also noted that KUCC had brought on Dr. Scott Berry, of Berry Consultants LLC, as an adjunct faculty member to help in the area of clinical trials. The KUMC web site still lists Dr. Berry as adjunct faculty. However, the current submission does not say anything about the role he played, what he accomplished, or whether he is still affiliated with the CCSG/BISR in any way nor do they report any data on how the quality of clinical protocols has improved, nor on what they are doing currently to ensure that improvements will be maintained.

Many of the faculty involved in BISR publish methodological papers developing novel methods to support the needs of cancer center researchers, having published 56 methodology papers in the last year. One expects that the majority of publications and grant proposals submitted by KUCC members will require biostatistical and/or bioinformatics support. Given that fact, the data on users of BISR is lower than one would expect. (This phenomenon is not likely to be unique to KUCC, since many institutions have difficulty collecting this data.). Over the current funding period, they have supported 69–78 users per year, which is roughly 40-45% of the 171 KUCC members. They report supporting 155 publications over the same period, which is only 6.4% of the 2411 publications reported by the KUCC as a whole. It was explained at the site visit that BISR was reporting one year of data and not the whole five-year funding cycle. They also report supporting 340 grant applications or projects, of which 36 were funded, 24 by the NCI.

The future plans described by the BISR are primarily on the information technology side. They will enhance the Curated Cancer Clinical Outcomes Database (C3OD), implement an eConsent tool for the Biospecimen Core, etc. Although there are plans to recruit for two informatics position (software engineer and a medical/health informaticist), how they identified these priorities, or how they will set priorities moving forward remains unclear.

It is also worth noting that BISR's Specific Aim 4 focuses on education, which is clearly aligned with one of the KUCC strategic goals. The amount of education provided by BISR looks fairly small (a five-day summer course led by one faculty member, and one-day training for IPA). There is both a need and an opportunity to increase the level of training. Doing so would also serve to introduce more KUCC

members and trainees to the resources available to them through BISR. At the site visit, they clarified the amount of training was much larger than described in the application and put it into context with the spectrum-wide training plans from the CRTEC presentation.

The quality of BISR appears to be high, as does the cost effectiveness. KUCC members are supported free-of-charge for proposal preparation, study design, and preliminary data analysis to formulate new hypotheses for proposals to be submitted for funding. About one-third of KUCC members use the SR every year, suggesting that the services are readily available. The qualifications of the core directors are first rate. Combined effort of the two co-directors is 1.8 calendar months per year, but they are supplemented by additional effort from faculty who lead the sub-units.

In summary, this is a strong shared resource consisting of an experienced team that provides an essential service for KUCC investigators, and it is rated outstanding. Services are provided for the majority of KUCC members that have resulted in grant submissions that in turn, now provide funding. A minor concern is the lack of clarity on how they set priorities and ensure that they are aligned with the KUCC strategic vision.

Assessment: Outstanding merit

Budget: The budget is appropriate as requested.

Clinical Pharmacology Shared Resource

DESCRIPTION (provided by applicant): The first aim of The University of Kansas Cancer Center (KUCC) is to “Leverage unique assets to transform research discoveries from the laboratory and the clinic to drive new anticancer therapeutic development”. The Clinical Pharmacology Shared Resource (CPSR) provides critical technical and scientific support in clinical pharmacology that is absolutely required to achieve this aim. The overarching goal of the CPSR is to provide support to all KUCC investigators and their research teams throughout the lifecycle of a hypothesis-driven investigator-initiated clinical trial (IIT), from early development of trial concept through publication and follow-on grant application. The CPSR provides guidance to our investigators at no cost in dose, analyte and matrix selection, design of sampling schemes, pharmacodynamic endpoints, preparation of clinical trial protocols and data analysis plans, preparation of study-specific laboratory manuals, as well as PK and PK/PD data analysis and reporting. Once activated, the CPSR provides GXP-compliant sample acquisition, processing, short-term storage, and transfer of samples to study-defined sites for analysis. The CPSR provides validated and SOP-driven analysis of trial samples for identification and quantification of drugs, metabolites, and biomarkers using LC-MS/MS, biochemical, and immunochemical methods. Drug and biomarker data, whether generated in the CPSR or from other laboratories, then are used for parametric and nonparametric PK data analysis, PK/PD modeling, and population pharmacokinetics. In response to the needs of our investigators as well as growth in the KUCC research portfolio over the current funding period, we have and will continue to expand our range of available technologies and services required. Based on project demands for greater quantitative sensitivity, structural elucidation of drug metabolites, and for quantification of therapeutic and biomarker proteins, the CPSR is acquiring new LC-MS/MS instrumentation and expanding its capabilities in immunochemical methods. The CPSR works extensively with KUCC members through the IIT Steering Committee as well as the Disease Working Groups to identify opportunities to incorporate clinical pharmacology objectives into clinical trials. The CPSR not only provides direct scientific and technical support for the design, but also enhances productivity and quality of clinical

research by educating all members of the research team on the goals of clinical pharmacology and the interactions between team members to achieve these goals. In short, the goal of the CPSR is to provide guidance and technical support to KUCC transdisciplinary teams across research programs to ensure that our IITs evaluate new cancer therapeutic and prevention agents in patients, optimize the utilization of existing anticancer agents, identify new cancer therapeutic and prevention indications for FDA-approved non-cancer drugs, and define the basis for variability in therapeutic and toxic responses observed in patients.

CRITIQUE: The Clinical Pharmacology Shared Resource (CPSR) was established as a developing resource in 2012 and in 2015 was selected as an established resource. The CPSR provides scientific expertise and technical support for clinical and population-based studies of therapeutic, cancer prevention, and cancer population investigator-initiated trials (IITS). The CPSR has three components, (1) the Correlative Laboratory (CL) charged with acquisition, processing, and transporting clinical research samples, (2) the Bioanalytical Laboratory (BL) which analyzes biomarkers, including drug concentrations and metabolites, in human samples, and (3) the Pharmacokinetics Unit (CPU) which designs pharmacokinetic studies, and analyzes and interprets pharmacokinetic and pharmacodynamic data, primarily in relation to drug exposures and responses. To date, the CPSR has supported 73 KUCC members, most with multiple clinical trials, as well as 10 non-KUCC investigators. There are educational programs offered to new KUCC clinical research associates, health providers, study coordinators, and others during their onboarding process.

In response to the previous review on the relatively small number of users, seemingly heavily weighted to the Drug Delivery and Experimental Therapeutic (D3ET) program, the CPSR has demonstrated a steady increase in the number of users (more than doubled in the past four years) across three programs - D3ET, Cancer Biology (CB), and the relatively new Cancer Prevention and Control program (CPC). There is no information provided about whether CPSR services have been utilized by new consortium partner investigators or if there has been outreach directed at these investigators. The process for investigators to learn about and request services was not included.

The CPSR is an important contributor to the Center and provides access to state-of-the-art capabilities. For example, the CPSR investigators describe a major KUCC accomplishment in which they were active participants in the development and testing of Fosciclopirox for the treatment of urothelial cancer under an NCI SBIR award. Their data supported a second trial, The Fosciclopirox Recommended Phase II Dose, Cystectomy, and the team was successful in subsequently securing NCI funding for a Phase IB/IIA trial in newly diagnosed and recurrent urothelial cancer patients which is ongoing. This would seem to be an excellent model for future research.

Future plans for the CPSR appear to be well-aligned with the members' needs. There are plans to add staff members to support the growth of new clinical trials and additional space is being acquired at community-based clinical trial sites for sample processing and short-term storage. Additional equipment is being purchased to support routine and new developments in bioanalysis. Finally, an oncology clinical pharmacology training program including training to analyze PK and PK/PD data is under development.

The resource clearly provides value in enhancing the translational and inter-disciplinary efforts of the clinicians and scientists in designing and carrying out clinical protocols. Over the current funding period, the number of users has increased steadily from 23 in 2016 to 51 in 2020 from all three programs (CB/CPC/D3ET). CPSR has supported 73 distinct KUCC members, most with multiple trials. In the

number of examples provided, CPSR has provided essential services and enhanced value for the IITs. Overall, the resource has added tremendous value to the first aim of KUCC “Leverage unique assets to transform research discoveries from the laboratory and the clinic to drive new anticancer therapeutic development”. The CPSR now supports 200 active cancer therapeutic and prevention trials conducted at each of the KUCC clinical research facilities. However, while there are clear examples of PK services provided on varies projects, example is not provided on the PD studies in clinical trials, which is important for today’s molecular-targeted clinical trial.

The CPSR is led by Dr. Paul Toren, who replaced Dr. Gregory Reed (retired) in 2020. Dr. Toren has more than 30 years of experience in both industry and academia developing and validating quantitative LC-MS/MS assays for drugs, metabolites and biomarkers in human and animal samples. Dr. Toren also serves as Director, Children’s Mercy Clinical Pharmacology and Toxicology, a position he has held since 2018. He is supported by Dr. Scott Weir, Clinical Pharmacokinetics Unit Director (new to this position since the previous application) and LaToya Berry, Director, Correlative Laboratories. Dr. Berry has served in this role since 2015. Dr. Weir also serves as co-chair of the Investigator Initiated Trial Steering Committee. The leadership and staff are well-qualified.

Assessment: Outstanding merit

Budget: The projected operating budget for next year is estimated at $1,261,180 with 4% from CCSG ($56,513), 3% from KUCC ($33,766), 43% $546,581 from institutional funds and 50% from fee for service activities $625,000. As in the previous application the budget is salary-focused with funds requested for the Executive Director, Dr. Toren, Drs. Weir and Berry, and a Senior Scientist who develops, validates and applies bioanalytical methods to support clinical trials and will lead the expansion of immunochemical methods and platforms, among other things. The budget is appropriate as requested.

Flow Cytometry Shared Resource

DESCRIPTION (provided by applicant): The University of Kansas Medical Center (KUMC) Flow Core was founded through an NIGMS-funded COBRE program (P20RR016443/P30GM103326) in 2006. The Flow Core quickly grew to be an essential component of the infrastructure of the KUMC research community, as well as The University of Kansas Cancer Center (KUCC). With over one-third of Core users being Cancer Center members, the Flow Core was elevated to a Cancer Center Shared Resource in 2018 after review by Matthew Mayo, PhD, MBA, FASA, Associate Director for Shared Resources. and Cancer Center leadership. The mission of the Flow Cytometry Shared Resource (FCSR) is to provide access to state-of-the-art flow cytometry and related technologies to all KUCC members. The FCSR is led by the Scientific Director, Mary Markiewicz, PhD (CB), and maintains two-full time staff, a Technical Director, Richard Hastings, MS, and a Research Assistant, Tykeemi Manor, BS. The FSCR houses a BD LSR II and Attune NxT for cell analysis and a BD FACSAria IIIu for cell sorting. In addition, the FCSR houses a Luminex 200 for multiplex analysis of cytokines, chemokines, and other small molecules. The FCSR aids investigators in experimental design, protocol development, sample preparation, data acquisition, and data analysis. Additionally, the FCSR has strong procedures in place for quality assurance, training, scheduling, data storage, and data analysis. Over the past three years, the FCSR provided key services in support of 25 publications to KUCC members (five papers ≥ 10 journal impact factor), 41 unique users, and four NIH/NIGMS/NCI grants, one DOD grant, and four private foundation awards, and was essential to analysis of human samples for correlative studies from an NCI-funded clinical trial (R37CA218118, NCT01868087). In the reporting year (2020), the FCSR

supported 34 different users (28 KUCC members from all three research programs, of which 75% were funded and six non-members). The proposed budget of the FCSR (Year 11) is $283,970, yet the CCSG request is $15,014. As such, the FCSR leverages grants, contracts, user fees, and extensive institutional support and seeks only 5% support from CCSG funds.

CRITIQUE: The mission of FCSR, which was founded through an NIGMS-funded COBRE program (P20RR016443/P30GM103326) in 2006, is to provide flow cytometry-based analysis and cell sorting service to KUCC members. This facility, which is located at KUMC was declared a KUCC shared resource after its cancer investigator users reached more than 30% in 2018. Hence, this is a new KUCC shared resource since 2018. The aims of FCSR are (1) Operate a state-of-the-art flow cytometry analyzer and cell sorter as a regional resource for KUCC members; (2) Provide full technical service and data analysis for high parameter flow cytometry; (3) Provide training in flow cytometry data acquisition and analysis for KUCC members.

The facility is directed by Dr. Mary Markiewicz, Associate Professor with more than 25 years of experience in flow cytometry. The FSR has also a full-time technical Director Richard Hastings, MS and a Research Assistant Tykeemi Manor, BS. The facility has currently one flow analysis (BD LSRII) and one sorting (BD Aria III) instrument. In addition, FCSR provides Multiplex cytokine analysis supported by a Luminex 200 instrument.

The FCSR has aided investigators in experimental design, protocol development, sample preparation, data acquisition, and data analysis. Additionally, the FCSR has strong procedures in place for quality assurance, training, scheduling, data storage, and data analysis. Over the past three years, the FCSR provided key services in support of 25 publications to KUCC members (five papers ≥ 10 journal impact factor), 41 unique users, and four NIH/NIGMS/NCI grants, one DOD grant, and four private foundation awards, and was essential to analysis of human samples for correlative studies from an NCI funded clinical trial. In the reporting year (2020), the FCSR supported 34 different users (28 KUCC members from all three research programs, of which 75% were funded and six non-members).

Given the size of KUMC and KUCC including the expanded consortium, both the instrumentation and number of staff seems modest. Nonetheless, an instrument grant for a state-of-the-art new Flow cytometer instrument has been submitted. To address the concern that the flow cytometry services are limited to a single site within the multi-site KUCC consortium, an advisory committee was formed to advise the FCSR Director and KUCC leadership on FCSR needs. Future plans also describe providing immunophenotyping services to support clinical trials in the immune-therapy area which is innovative but will further increase the need for instrument upgrades, innovation and expanding of staff to serve the different consortia sites.

In summary, this is a relatively new KUCC shared resource, which provides services to all KUMC investigators and KUCC members. Strengths are the experience of the director, a steady userbase, its track record to support both papers and successful grant submissions. However, the modest current instrumentation requiring both updating and expansion, has been recognized by KUCC leadership. Furthermore, there is inadequate information about how FCSR services are provided to KUCC investigators across the different consortium sites and how investigators satisfaction with the provided services is monitored.

Assessment: Excellent to very good merit

Budget: The budget is appropriate as requested.

Lead Development & Optimization Shared Resource

DESCRIPTION (provided by applicant): The Lead Development and Optimization Shared Resource (LDOSR) is a shared resource of The University of Kansas Cancer Center (KUCC), composed of three component laboratories located on the KU Lawrence West Campus: High-Throughput Screening (HTS), Medicinal Chemistry (MDCM) and the Biopharmaceutical Innovation and Optimization Center (BIOC). LDOSR provides preferred access to KUCC members to accelerate projects from drug-target discovery through high-throughput screening, compound hit prioritization, secondary in vitro confirmatory assays, medical chemistry optimization, in vitro pharmacology testing, in vivo pharmacokinetics, and drug delivery formulations for in vivo preclinical proof-of-concept testing. The activities involved with the generation, evaluation, and optimization of drug candidates is an iterative process that crosses several scientific disciplines. The LDOSR has been structured to optimize services under a single, easy-to-access umbrella, with oversight from the Director and a team of project managers, allowing projects to move seamlessly between component laboratories. Comprehensive plans tailored to fit each project's needs ensure users get the most relevant data to move their projects forward. Additionally, the LDOSR offers drop-in ready grant submission and publication language. Over the past five years (2016-2020), the LDOSR has supported 167 KUCC member projects (~76% were peer-review funded). The LDOSR leverages research infrastructure established, historically, through internationally recognized medicinal and pharmaceutical chemistry research conducted by the University of Kansas School of Pharmacy. Added to this is the availability of industry experienced scientists from former area Pharma and CRO companies. The LDOSR has successfully recruited top-notch scientists with industry and academic qualifications to lead and staff the three component laboratories. The LDOSR, working with the Associate Director for Translational Research, established the Drug Discovery and Development Steering Committee. This translational-research catalyst provides a forum for KUCC investigators to develop research concepts at the chemistry/biology interface with support from the LDO laboratories. The LDOSR partners with The Institute for Advancing Medical Innovation to advance drug discovery projects through early drug development, actively conducting and supporting studies necessary to enable first-in-human clinical trials. Additionally, LDOSR staff serve on the Investigator-Initiated Trial Steering Committee, which facilitates evaluation of development candidates in early phase experimental therapeutics trials conducted by the D3ET research program. Lastly, bioanalytical methods for determination of drug and metabolite concentrations in preclinical matrices, are transferred to the Clinical Pharmacology Shared Resource where they are cross-validated in human matrices under GLP conditions to support early phase clinical trials. The result is a fully integrated, end-to-end translational research function capable of advancing novel cancer therapeutic agents invented by KUCC members to clinical trials.

CRITIQUE: The Lead Development and Optimization Shared Resource (LDOSR) is a KUCC shared resource composed of three component laboratories located on the KU Lawrence West Campus: High-Throughput Screening (HTS), Medicinal Chemistry (MDCM) and the Biopharmaceutical Innovation and Optimization Center (BIOC). The LDOSR provides preferred access to KUCC members to accelerate projects from drug-target discovery through high-throughput screening, compound hit prioritization, secondary in vitro confirmatory assays, medical chemistry optimization, in vitro pharmacology testing, in vivo pharmacokinetics, and drug delivery formulations for in vivo preclinical proof-of-concept testing. The activities involved with the generation, evaluation, and optimization of drug candidates is an iterative process that crosses several scientific disciplines. The LDOSR has been structured to optimize services under a single, easy-to-access umbrella, with oversight from the Director and a team of three

project managers, allowing projects to move seamlessly between component laboratories. Comprehensive plans tailored to fit each project's needs ensure users get the most relevant data to move their projects forward.

Dr. Amanda Brinker appointed as the Director of the LDOSR, has three years of experience as Deputy Director of Institute for Advancing Medical Innovation and KUCC Assistant Director of Translational Science, and six years of industry experience in high-throughput enzyme and cell-based assay design and optimization, pre-clinical animal model selection, drug repurposing and discovery, and early ADME Toxicology. Dr. Brinker is responsible for coordination of the efforts across the three groups within LDOSR.

Dr. Anuradha Roy serves as Manager HTS Component and Research Lab Director. Dr. Roy has 25 years' experience in assay development and HTS and is expert in assay method development for biochemical, cell-based, biophysical, and phenotypic screens; assay miniaturization, validation; large compound library handling; hit identification/confirmation/ prioritization, and large data analysis.

Dr. Frank Schoenen serves as Manager of MDCM Component and is the Director KUCC MDCM. Dr. Schoenen has 15 years' experience as a medicinal chemist and manager in the pharmaceutical and biotech industry and 16 years of experience in the academic setting as the Associate Director for the NIH-funded Chemical Methodologies and Library Development Center and the NIH-funded Molecular Libraries Probe Production Centers Network. As MDCM director, Dr. Schoenen is responsible for all aspects of compound design and synthesis, and SAR supporting hit compound optimization, as well as financial operations.

Dr. Michael Hageman serves as Manager BIOC Component and Director of BIOC. Dr. Hageman has 36 years' experience. As Director of BIOC, Dr. Hageman leads staff and project management with the LDO component. Leads design of all studies and overseas financial operation. Each of these three managers for each component is supported by experienced project managers and staff scientists.

Overall, LDOSR is a multifactorial service, which requires strong coordination to drive the process of drug discovery. The LODSR services have been provided to 167 KUCC members during the last five years and more than 76% have been investigators supported by peer-reviewed funding. Importantly, services were provided to investigators from all three programs. While it was not clear what was the usage of the High-Throughput Screening (HTS) in the CCSG grant application, at the site visit it was made clear that 17 and 19 screens were performed in 2021 and 2020, respectively, representing a very good usage. The Medicinal Chemistry plays a critical role in advancing a drug discovery program from "hits" to optimized lead compounds. Among the three examples highlighted, one project (Targeting Kif15-TPX2 Interaction in Ovarian Cancer) made excellent use all of the three components with LDOSR, and the other two projects are collaborations with external investigators and made extensive use of the expertise of Dr. Schoenen.

While the success of the MDCM Component is well documented with either internal or external collaborations, the success of HTS or BIOC was not well documented. Although the highlighted examples are helpful, additional metrics with respect to tangible outcomes (number of funded grants and publications) needs clear documentation. Furthermore, number of services provided in the three subcomponents is not described in the grant application, but some of these were clarified at the site visit. In summary, this shared resource is very valuable for translation of targets to eventual clinical

trials of KU-invented agents. The LDOSR core has provided a service to a large number (176) of KUCC members in the last five years.

Assessment: Outstanding merit

Budget: The budget is appropriate as requested.

Nutrition Shared Resource

DESCRIPTION (provided by applicant): The Nutrition Shared Resource (NSR) co-directed by Debra Sullivan, PhD, RD, and Jill Hamilton-Reeves, PhD, RD, CSO, facilitates an important aspect of addressing the cancer risk factor of obesity as a priority area for The University of Kansas Cancer Center (KUCC) by providing support for basic, clinical and population health research evaluating the effects of nutrition on cancer therapies, cancer prevention and cancer population health. The NSR offers quantitative measurements of dietary intake, physical activity, nutrition status/malnutrition assessments, standardized diets, body composition, microbiome, and nutrition literacy. NSR services also include design and implementation of interventions to adhere to specific diet or physical activity goals. The NSR provides expertise in oncology nutrition, diet assessment, intervention design, energy balance, body composition, gut microbiome, and nutrition literacy. The faculty and staff of the NSR oversee the measurements and/or services as required for each study. NSR maintains licensed copies of the Nutrition Data System for Research (NDS-R) and Nutrascreen for dietary intake assessments. The NSR maintains software and instrumentation such as the sliceOmatic, DXA, Bod Pod, Tod Pod, and Pea Pod, and the Bodystat Quadscan 4000 bioelectrical impedance analyzer to assess body composition across the lifespan or at the bedside/clinic for cancer therapeutic trials. Handgrip dynamometers and skin carotenoid meters are other instruments frequently used for nutrition assessments. Services are provided on-site at the KU Clinical Research Center (CRC), Westwood and KU Hospital locations, as well as via outreach to Masonic Cancer Alliance (MCA) partners, sites across the KUCC catchment area, and external NCI-designated cancer centers. The NSR collaborates with communities throughout the catchment area using community screenings and outreach with special emphasis in underserved and rural populations. The NSR was a key resource for KUCC adapting obesity as a priority area. The NSR has grown from its inception in 2016 from a developing shared resource to a full shared resource. During this development phase, NSR annual usage grew from zero to 30 KUCC members with a total of 61 distinct members across all programs. In the reporting year (2020), the budget of the NSR is $959,579. The NSR has robust peer-supported funding with 83% of the budget supported by other grants. The NSR trains and educates the next generation of oncology scientists and health care professionals through collaborative research and outreach efforts with the MCA. The NSR regularly incorporates trainees at all levels within projects and prioritizes support for early stage investigators.

CRITIQUE: Established as a KUCC developing shared resource in 2016, the Nutrition Shared Resource (NSR) provides expertise in a wide range of areas including diet assessment, oncology nutrition, intervention design, measures of energy balance, body composition, and body fat distribution, the gut microbiome and nutrition literacy using state-of-the art software (e.g., the Nutrition data System for Research) and equipment (e.g., dual energy x-ray absorptiometry (DXA), Bodpod). The NSR contributes to community outreach by participating in community screenings and other outreach activities, especially in areas of underserved and rural populations. The specific aims of this core are to provide guidance on nutrition study design, implementation, analysis, and dissemination, to provide

technical nutrition services, to service KUCC members with trained dietitian counselors, and to educate KUCC researchers, trainees, and the catchment area about cancer and nutrition.

Services are provided at the KU Clinical Research Center (KUCC), at KU Hospital locations and community locations across the catchment area. These services are provided by 6 PhD trained faculty members and 5 staff, all of whom have particular areas of expertise to bring to the group.

Since its inception, the NSR reports serving a total of 61 KUCC members across all programs, and annually, a range of 17-30 KUCC members. Usage of the shared resource was highest from the CPC program, with 17 users, and seven members of CB and six members of D3ET used the resource in 2020. The team provided support that led to 26 publications during the developmental phase of the shared resource. The scientific highlights include assessment of how nutrition literacy predicts diet patterns in those with cancer, challenges of rural breast cancer survivors in trying to keep weight off, associations of diet with inflammation and microbiome, and feasibility of weight management in prostate cancer patients. The total dollars of external funding to support the shared resource was 800,000, and the NSR supported 23 funded grant applications in 2020. It is unclear how many grants make up this external funding, or the types of funding. At the site visit the leadership indicated there was a grant from American Cancer Society and a least one other from the NIH.

Contact with the user base internally is through seminars and the annual KUCC Research Symposium and externally through presentations at national meetings and through the KUCC website. A process for access and prioritization is in place. Currently access is by contacting either co-director, although it is not clear whether this is by email/phone or there is an online service request system available to facilitate and track requests. The NSR prioritizes support to all KUCC investigators based on the overall guidelines for Shared Resource Management, with prioritization for peer-reviewed, funded research projects. This is understandable given the limited budget; however, there may be missed opportunities for involvement in future research if the NSR is not able to provide support to pilot research.

Overall, it is not clear how well the NSR is meeting the scientific needs and objectives of the Center and cost-effectiveness of the NSR was not adequately addressed. Stronger and more widespread application of nutrition science services to KUCC research has the potential to further increase the impact of member research on the catchment area. Additional details regarding the characteristics of the populations served and reach are needed in support of NSR accomplishments. For example, the NSR reports providing key services in support of 26 manuscripts, but details related to what and the types of services provided are not well addressed (e.g., survivors, clinical patients, those interested in cancer prevention and control in community settings), demographic characteristics, and number of participants/patients reached through these activities. Four examples of manuscripts were highlighted which were published in respected nutrition or medical journals. Unclear is if NSR members were included as co-investigators on these and/or other cancer-related research projects. Training and educational opportunities are offered to clinical dietitians across Kansas, but details on how many offerings or the number of providers reached to gauge how successful this activity are not apparent. Additionally, the application does not adequately address how many community members were reached through screenings and other activities. In the Future Plans section, the NSR proposes to enhance their user tracking system with a project registration database. This should facilitate usage tracking and improve reporting going forward.

The NSR is co-directed by Debra Sullivan, PhD, RD and Jill Hamilton-Reeves, PhD, RD, CSO, who are well-qualified to serve in this capacity. Dr. Hamilton-Reeves, Associate Professor in the Department of

Urology, is a board-certified oncology nutrition dietitian. Her responsibilities to the shared resource include quarterly faculty operations meetings, collaborations with members to develop grants and protocols, and co-leading educational and community outreach activities. Dr. Sullivan, Professor in the Department of Dietetics and Nutrition, is also Director of the Nutrition Core funded by the Kansas CSTA award. Dr. Sullivan's responsibilities for the NSR include quarterly faculty operations meetings, collaborations with members regarding protocols and grants, and co-leading educational and outreach activities, as well as recruiting new nutrition faculty. Six PhD-trained faculty members and seven other colleagues, including postdoctoral fellows and masters' level staff, are available to support projects.

In summary, the goals of this core are to provide guidance on nutrition study design, implementation, analysis, and dissemination, to provide technical nutrition services, to service KUCC members with trained dietitian counselors, and to educate KUCC researchers, trainees, and the catchment area about cancer and nutrition. A broad range of nutrition-related services are available at the KU Clinical Research Center (KUCC), at KU Hospital locations and community locations across the catchment area. These services are provided by six PhD trained faculty members and five staff, all of whom have particular areas of expertise to bring to the group. With the addition of tangible, better-defined metrics and tracking will demonstrate how well the NSR is meeting the needs and objectives of the KUCC.

Assessment: Excellent merit

Budget: The KUCC has invested $125,000 in the NSR as developing shared research over the past five-year grant period. Going forward the Co-directors will receive 10% salary support, two research dietitians will receive salary support and partial salary support for a new PhD, RD diet and cancer faculty member is planned (although the level is not stated). The major portion of the operating budget for the NSR is funded by other grant support and to some extent by fee for service. The budget is appropriate as requested.

Transgenic & Gene-Targeting Shared Resource

DESCRIPTION (provided by applicant): Genetically altered models are important tools for the researchers at The University of Kansas Cancer Center (KUCC). The production and analysis of such models using CRISPR-based genome editing methods, including mouse, pluripotent stem cell, and tumor cell line models, ultimately leads to a better understanding of the nature, progression, and functional genomics of tumor formation. Genetically engineered mouse strains also serve as in vivo models for diagnostics and treatment. The techniques employed to generate genetically modified animal and cell models require specialized equipment and technical expertise. The Transgenic and Gene-Targeting Shared Resource (TGTSR) led by Jay L. Vivian, PhD, supports members of KUCC by providing centralized and comprehensive technical services for the production of novel genetically engineered rodents and cell lines. The TGTSR uses cutting-edge methods, state-of-the-art instrumentation, and novel reagents for the generation of these models. Genome editing methods are central to the activities of the TGTSR, including a pipeline for the design and optimized use of CRISPR reagents in embryo and cell models. The expertise of the TGTSR Director and staff is leveraged in all phases of the generation of novel genetically engineered models, from the initial experimental design stage through model generation, molecular characterization, expansion, genotyping, and cryopreservation. This extensively used shared resource supported 28 KUCC users in CY2020, and 49 unique KUCC members were supported by the TGTSR in the previous funding period, demonstrating the broad use of this shared resource. The five full-time staff members of the TGTSR include the coordinated efforts between staff at both the University of Kansas Medical Center (KUMC) and

Children's Mercy Kansas City (CM) campuses, allowing for staff expansion in response to increased use by KUCC members. By centralizing operations and reagents between KUCC consortium members, all services are available to KUCC investigators on all campuses at a greatly reduced time and cost. The Cancer Center support of the TGTSR allows for the development of specific initiatives relevant to cancer research. For example, certain transgenic methods and mutations are particularly relevant to cancer studies, including tissue specific transgene expression and subtle mutations that recapitulate clinically identified variants and somatic mutations. Strategic investments by the KUCC have allowed for acquisition of new instrumentation and support to develop novel CRISPR mutagenesis methods in the zygote and in cell lines. The integration of these continually evolving methods into the 'toolbox' of the TGTSR greatly accelerates the development of animal and cell models of cancer, while also reducing costs to KUCC researchers on all campuses.

CRITIQUE: The Transgenic and Gene-Targeting Shared Resource (TGTSR) is a relatively new shared resource, created in 2009. Services include using state-of-the-art CRISPR-based genome editing methods to produce genetically engineered rodent models and animal and human cell lines, education of KUCC members on new technologies, and sperm and embryo cryopreservation services. Specific methods include mouse embryo manipulation services, karyotyping, and establishment of human primary fibroblast cell lines from skin biopsies. These technologies are not feasible for most individual laboratories but are critical to supporting and growing the KUCC research portfolio in a cost-effective manner.

The TGTSR has been led since its inception by Dr. Jay Vivian, who holds a PhD in developmental genetics and is supported by a staff of five, providing sufficient personnel to reduce project support queues, especially for the embryo microinjection services. All are well-qualified for their roles. Services have been integrated across the Children's Mercy and KUMC sites into a single inter-consortium shared resource, with staff at two sites to support location-specific needs such as pathogen-free animal strains. Sufficient personnel to reduce project support queues, especially for the embryo microinjection services.

In 2020, TGTSR has served 28 users from all three programs with a majority of services delivered to CB members (20). Over the last five years a total of users has been relatively constant fluctuating between 20 and 28. Fee for service chargebacks account for 25-33% of its operating budget, and there is excellent institutional support. However, details about the number of papers or the number of grant submissions, awards supported by TGTSR services is not well addressed; a missed opportunity to highlight its impact. Future plans include expanded production services for cell line mutagenesis, NGS methods for analysis of CRISPR models, further integration of mouse model efforts between KUMC and CM, and purchases of new equipment.

The TGTSR is a very strong shared resource, providing essential services to KUCC and other investigators. Under Dr. Vivian's leadership, the shared resource has incorporated cutting edge technologies and is proactive in anticipating future demands, not just responding to investigators' current needs. Further opportunities of growth and impact maybe to provide phenotyping services for their transgenics and to expand their services into organoid models.

In summary, TGTSR provides a number of state-of-the-art services, consults, trains and supported 49 KUCC investigators over the last 5 years. The number of services provided is impressive. While this is suggestive of high impact for TGTSR on KUCC, the narrative as presented lacks a detailed analysis of outcome metrics (number of papers and grants supported) user satisfaction data, and innovation in the

future plans. Nevertheless, this does not distract from the overall high enthusiasm for this shared resource which was unanimously ranked outstanding.

Assessment: Outstanding merit

Budget: The budget is appropriate as requested.

CANCER RESEARCH TRAINING AND EDUCATION COORDINATION

DESCRIPTION (provided by applicant): The University of Kansas Cancer Center (KUCC) Cancer Research Training & Education Coordination (CRTEC) component coordinates and provides essential cancer-focused education, training, and career enhancement annually for >500 trainees and ~200 healthcare professionals. The CRTEC team and leadership (Danny Welch, PhD and Lisa Harlan-Williams, PhD) works closely with Community Outreach and Engagement (COE) and educators from four KUCC campuses to increase education and outreach to diverse populations and cultivates an environment of lifelong learning throughout our catchment area. KUCC faculty actively participate in training high school through post-graduate researchers in multiple biomedical and healthcare fields by coordinating and integrating cancer education at all KUCC campuses. KUCC faculty have developed new doctoral and certificate programs, provided research experiences (including for underrepresented populations (URP) in the Kansas City metropolitan area); provided medical and nursing continuing education curricula; developed specialized senior-to-junior mentoring and facilitated peer-to-peer career development; assisted with grant preparation for faculty and trainees, and supported trainee travel. CRTEC is leading institutional development of an integrated system for tracking and assessment of trainee outcomes. KUCC trainees have made discoveries in basic, translational, clinical, and population science, received numerous honors and awards, publications, and experienced >3-fold increase in extramural fellowship funding since NCI designation. CRTEC is guided by three aims: 1) Continuously enhance an infrastructure that facilitates center-wide training and educational programs that enrich collaborative and interdisciplinary basic, clinical, translational, and population-based cancer research by engaging investigators from multiple cancer-relevant research disciplines and backgrounds via a diverse collection of scientific and educational initiatives; 2) Provide cancer research education and career enhancement opportunities across the continuum of trainees and faculty, through stage-specific scientific and professional development activities that promote and sustain a strong pipeline of diverse investigators and cancer care providers; and 3) Prepare KUCC researchers to work with COE, community leaders and advocates, KUCC research programs and shared resources to educate learners and teachers within KUCC and throughout the catchment area. These aims will help fulfill the CRTEC vision – that learners receive high quality education, training, and mentoring so that a well-trained, motivated, diverse, and equitable workforce of investigators and care providers can reduce cancer burdens locally and beyond.

CRITIQUE: The aims of CRTEC, a new programmatic initiative, are to enhance the KUCC infrastructure for training and education, provide cancer education and career enhancement across the continuum of trainees and faculty, and prepare KUCC members and trainees to engage in outreach efforts. The CRTEC is headed by Drs. Danny Welch and Lisa Harlan-Williams. Drs. Welch and Harlan-Williams also serve as Associate Director and Assistant Director of Education, respectively, under the newly reorganized KUCC structure. The Vice-Chancellor of Academic and Student Affairs, ensures that all educational programs are accredited and that professional advancement initiatives are appropriate. Dr. Welch oversees programming, inter-campus coordination, policy related issues, and grad student/postdoctoral training while Dr. Harlan-Williams oversees high school and undergraduate

training, outcomes monitoring and diversity programming. Recognizing the need for these initial efforts to mature somewhat, a future goal will be to integrate activities across the learning spectrum.

Over the current funding period the KUCC participated in 24 training grants, of which one was NCI-funded, 20 were NIH-funded and three were from peer-reviewed non-NIH sources. The low proportion of NCI funding raises concern about the cancer focus across the training portfolio. The KUCC leverages Frontiers (i.e., KUMC CTSA) in its training programs, and supports two cancer focused KL2 awards. This is considered an important leveraging of resources. Further development will synergize both programs and it will be important to do this in a manner that leads to outgrowth of cancer focused programs.

Three new graduate programs were developed, including in Cancer Biology, Biostatistics and a graduate program at Stowers. Additionally, the KUCC onco-psychology program was accredited in 2019, in partnership with KU-L, providing advanced practicum, American Psychiatry Association Accredited, pre- and postdoctoral training. These are important accomplishments, several newly initiated, and some very creative. Several educational forums, such as scientific lecture series, are in place and extend to all consortium institutions. Strategies for implementing bidirectional education efforts to engage learners in community outreach were presented at the site visit and felt to be very innovative.

However, beyond the current strategies, there is inadequate description of the plans for achieving the proposed aims. For example, not well addressed is how outcomes tracking and needs assessment data will be used to increase the success rate of KUCC trainees and URP representation and defined metrics and benchmarks is not evident.

An Office of Cancer Career Development (OCCD) was formed with representation from all consortium partners and responsibility to coordinate activities, plan new initiatives and evaluate outcomes. This is considered a key office for integrating education across sites. It is not yet clear how it functions. The Grants Development Office (GDO), established in 2010, provides assistance to KUCC investigators and trainees in preparing the non-scientific aspects of proposals for submission to funding agencies. In 2020, the GDO assisted 50 investigators with 116 proposals, which represented a 16% increase from 2018. This appears to be a powerful and creative resource. The “Grant Rounds” forum, created by Dr. Welch in 2012 to assist junior investigators in the development of grant proposals, has contributed to successful proposals for five junior faculty members in the Cancer Biology Program as well as numerous successful fellowship and training awards.

Dr. Welch has extensive and relevant experience, inclusive of over 30 years in academia, a track record of developing four cancer biology graduate programs at three large institutions, a robust mentoring record, and holding national-level committee leadership positions, including in the Cancer Biology Training Consortium, AACR Science Education/Career Advancement Subcommittee on Early Career Investigators, and has worked to define essential characteristics for CCSG cancer biology education, published as a white paper in Cancer Research.

Dr. Harlan-Williams, has relevant and complementary experience, including 25 years of education within the KU system. She has taught several scientific courses, inclusive of peer-led, team-learning Biology courses, teaches, guides and mentors PhD and MD/PhD trainees, served on many local committees. She worked with the Office of Diversity to develop a summer Accelerate Cancer Education

(ACE) program which provides a six-week summer research experience for underrepresented minority high school students. This work was described in the Journal of STEM Outreach.

Overall, the CRTEC program has been formed, is in the early phases of maturation, and is under sound and experienced leadership. Continued maturation should be a dedicated focus, with milestone goals of capturing cancer-focused training activities and grants.

Assessment: Outstanding to Excellent merit

Budget: The budget is appropriate as requested.

COMMUNITY OUTREACH AND ENGAGEMENT

DESCRIPTION (provided by applicant): Community Outreach and Engagement (COE) efforts are central to The University of Kansas Cancer Center (KUCC) achieving its mission to reduce the cancer burden in our catchment area (CA). COE is led by Ronald Chen, MD, MPH, Associate Director for Health Equity, and guided by the CA Steering Committee which includes KUCC leaders and community stakeholders. Hope Krebill, MSW, BSN, RN, serves as Assistant Director for Outreach and Executive Director of the Masonic Cancer Alliance (MCA), which implements COE activities throughout the CA. The KUCC CA consists of the state of Kansas and 18 counties in western Missouri, a total of 123 counties and 4.5M population; 78% of counties and 25% of population are rural. Aim 1: Identify, monitor, and evaluate the cancer burden and needs, and KUCC impact, in the CA. KUCC has developed a database called OPTIK (Organize and Prioritize Trends to Inform KUCC), which is used to monitor cancer incidence, mortality, screening, and risk behaviors in the CA. These data are reviewed by the KUCC Community Advisory Board and the CA Steering Committee. KUCC selected priorities with the CA Steering Committee and Community Advisory Board input, which are: obesity, tobacco-related cancers, prostate cancer, breast cancer, gastrointestinal cancers, and hematological cancers. There is an additional focus on rural patients given the make-up of our CA. Aim 2: Engage stakeholders to stimulate cancer research and control activities. COE works with an extensive infrastructure creating bi-directional communication between KUCC and diverse stakeholders including patients, clinical providers, and hospitals throughout the CA, which helps KUCC set priorities for cancer research and control activities, and also collaborate in these activities to affect individuals throughout the catchment area. Aim 3: Catalyze research that addresses high-priority cancers and issues specifically relevant to the CA and as guided by community stakeholders to improve health equity. COE plays a critical role in stimulating and supporting KUCC research in four important ways: 1) By facilitating bi-directional communication with community members to define KUCC priority areas and communicating these priorities to KUCC program leaders and members in order to focus research activities toward these priorities; 2) by fostering collaborations between KUCC researchers and community collaborators, and training researchers on community-engaged research; 3) by driving continued efforts for KUCC to focus on the unique needs of rural cancer patients in the CA; and 4) by creating and operationally supporting an infrastructure throughout the CA that can be leveraged for research. Aim 4: Drive, disseminate and implement cancer control activities and policies to reduce cancer burden in the CA in collaboration with community stakeholders. These activities include cancer screenings, implementation of evidence-based interventions, public education, supporting community cancer centers, and influencing health policy. A detailed evaluation framework and future directions will enhance efforts related to these specific aims.

CRITIQUE: The KUCC COE program is led by Dr. Ronald Chen and supported by Ms Krebill. The program has exceptional depth and breadth, with programmatic activities that are well integrated within all the scientific programs with demonstrated impact, and a wide breadth highlighted by the geographic spread and outreach activities with various communities within the KUCC catchment area

Some of the important accomplishments of the COE program members include: 1) the detailed analytic infrastructure (OPTIK) supporting catchment area demographics and evaluation and assisting with clinical trial feasibility and catchment relevance; 2) the patient advocacy perspective (PIVOT) integrated into COE and cancer center activities; 3) the Masonic Cancer Alliance and KPPEPR networks that has extended the reach of KUCC to primary care and rural providers within the catchment area; 4) the strong and consistent bi-directional communication channels between KUCC leadership, researchers, and community members; and 5) the community advisory board that provides ongoing feedback to researchers, with demonstrated impact with the manuscript authored by community cancer survivors. As clarified during the site visit presentation, the enrollment of Hispanic patients, although lower than catchment area population is well justified epidemiologically, and coupled with extensive outreach efforts, including contracting with an external company to solicit feedback on the needs of the Hispanic community in catchment area. Equally impressive is the ongoing bi-directional relationship and quarterly meetings with tribal health-care leaders of American Indian communities in the catchment area.

KUCC defines its catchment area as the entire state of Kansas (105 counties) and 18 counties in western Missouri. There is considerable analysis and documentation of overrepresented cancers in the catchment compared to national statistics. There are unique challenges within the catchment area (CA) which is geographically large and very diverse, and most rural counties are designated primary care Health Professional Shortage Areas. KUCC demonstrates a clear understanding of the depth of these challenges. In 2016, 94% of KUCC cancer patients resided in one of the 123 catchment counties. About 40-45% of KUCC patients come from 18 Missouri counties, and the entire 123 county area covers >4.5 million people in urban, semi-urban, rural and frontier communities. The demographic of the catchment area is 85% White, 8% Black or African American and 10% Hispanic. There are special populations included in the CA, including frontier-dwelling elderly rural White families, growing rural and urban Hispanic population, American Indian communities (four reservations), immigrants and refugees from Asia, and poor rural individuals. An additional challenge for some rural Hispanic participants is lack of documentation/temporary immigration status. The definition and justification of KUCC CA has been well justified.

Based on review of OPTIK data, an integrated dataset of patient and clinical health data to inform trends developed by COE, the CA has identified priority cancer areas: tobacco related cancers; prostate, breast; GI cancers; hematologic cancers; obesity. The focus on tobacco related cancer is based on higher smoking prevalence (20% of adults in catchment area smoke) and lung cancer being the top mortality cancer and modifiable; prostate cancer being the most common cancer among men and second leading cause of death in men with stark disparities. Focus on hematologic cancer is justified as a top cancer burden for children, leukemia rates are higher than US average; and high rates of obesity in CA chosen as a behavioral priority. KUCC elevates the cancer research and control needs of its catchment area population through bidirectional relationships between the Community Advisory Board (CAB) and cancer center leadership.

KUCC has effectively established programmatic infrastructure to ensure bidirectional stakeholder participation across the spectrum of research. The CAB comprises 18 individuals of diverse cancer

experiences and meet quarterly. The CAB chair advises cancer center director, Ads and program leaders, and CAB serves as liaison to communicate KUCC efforts to communities and facilitate implementation of cancer control activities. Other programs include: the Masonic Cancer Alliance network, comprising of hospitals, community cancer centers and providers enable extended reach into under-represented communities i.e. rural and low income, and provide access to clinical trials. The KPPEPR (Kansas patients and providers engaged in prevention research) provides a platform for primary care providers to contribute to reducing cancer burden, improving screening and prevention efforts. JUNTOS and Faith Works Connecting for a Healthy Community are other programs leveraging expertise from Black and Hispanic communities to reduce cancer disparities. Since the center through the Masonic Cancer Alliance has such an expansive relationship with KPPEPR, Juntos for cancer, and Faith works for a Healthy community it appears that there is integration with disparities communities, their medical providers, for both cancer treatment and control measures. Further specific efforts in promoting education, screening, guideline implementation strives to be even across the catchment. NCI recognition and funding in 2019 of KUCC as one of just a few MU NCORP sites speaks directly to both the diversity of the cancer center and its commitment to community initiatives specifically in minority and underserved populations. Dr. Jensen, as the Cancer Center Director, has a direct line to state policy makers further strengthening the areas of importance to be addressed by legislature including laws around smoking age requirements. Parity for oral cancer drugs is a significant area of need across all cancers. Kansas has implemented such parity laws and leadership continues to spearhead federal initiatives for drug parity.

The CAB chair meets with cancer center director, AD and program leaders to discuss community priorities and engagement approaches, including proposing new priority areas, and serve as liaison to communities. The CAB also helps identify locations for new community cancer screenings, and advocate for a focus on priority health needs of the community. Another program, PIVOT (patient and investigator voices organizing together) aims to connect KUCC researchers with community members and is a mechanism for patient advocates to collaborate with researchers to inform ongoing studies. PIVOT currently has 120 diverse members and live throughout the CA. PIVOT has supported 45 research proposal submissions. Seventy-one researchers have engaged with PIVOT, representing all three research programs. The COE ensures that cancer research is relevant to patient by including patient voice in every step, promoting meaningful collaboration, and developing education and training for patients, caregivers, and researchers. Rapid reactor panel is highly innovative—one hour matching 5 PIVOT members with researchers for rapid feedback. The COE Administrative Supplement (P30CA168524-09S4, PI Chen) funded creation of a community engagement training program specifically for basic scientists. One dyad (Dr. Nikki Cheng/CB, Dr. Tracy Solis/PIVOT) already successfully applied for a KUCC pilot grant. Another dyad's (Dr. Sufi Thomas/CB, Dr. Cheryl Jernigan/PIVOT) letter of intent has been chosen for full grant proposal submission by the Department of Defense.

In 2020, 15% of clinical trial enrollees were from rural counties (78% of catchment area counties and 25% of population are rural). The NCORP grant focused on rural population to enhance participation in clinical trials, increased rural participation in clinical trial to 24%. The CATCH-UP supplement supported MCA network to enhance access to targeted cancer therapies for minority/underserved populations, achieving 67% of enrollment from this group. The COE supported CPC program in a P30 supplement to engage rural providers in cancer control research, including Accountable Care Organizations. Other activities include supporting obesity research with community cancer centers; mobile cessation support for Latino smokers, liver cancer pilot study leading to an R21 and R01 grants, etc. Other activities include partnering with MCA network hospitals for cancer screening in every KS county for 1,085

screenings in 2019; colon cancer education and screening, FIT kits and patient navigation to over 200 individuals; partnership with early detection works on breast and cervical cancer screening. One question is whether there is a plan to a sustain increased clinical trial enrollment among rural populations after the NCORP grant—how these strategies are integrated into cancer center, as a whole.

Dr. Chen joined as Associate Director for Health Equity in 2019 and oversees the COE program. At 20% effort, he provides overall leadership and oversees OPTIK database to monitor catchment area, engage stakeholders, catalyze research and evaluate EBI interventions to address catchment area priorities. Supported by Ms. Hope Krebill at 10% effort, she is director of the Masonic Cancer alliance, and oversees a team of community outreach staff to facilitate collaboration with community stakeholders. Dr. Chen is a well-established investigator with a robust research program focused on cancer disparities, care delivery and comparative effectiveness, and with using population-based data to evaluate cancer burden. His expertise and commitment is appropriate for leading the COE program. The alliances that have formed at the present time supply a lot more effort “in kind” for this program. The current team and its leader are well qualified for commandeering this effort

There is evidence of extended reach within and beyond the CA through participation by KUCC members in regional and national organizations for policy. This includes the Missouri Cancer Consortium, Kansas Cancer Partnership chair; Biden Cancer Initiative- Patient Navigation Working Group, National Lung cancer Screening Roundtable; NCI Clinical Trials and Translational Research Advisory Committee. Future plans are encouraging, including additional outreach to Black and Hispanic patients, mobile screening van, and collaborative COE pilot grants with PIVOT members. Cancer screening is imperative and at the site visit, clear plans were outlined to address suspected cancer cases that may result from these screenings. There are appropriate metrics in place for evaluation and a well-formed and expansive blueprint for the future. In summary, the KUCC COE program is considered exceptional with a solid infrastructure to continue to monitor and address community needs and adapt as the needs may change.

Assessment: Exceptional merit

Budget: The budget is appropriate as requested.

CLINICAL PROTOCOL & DATA MANAGEMENT, DSM, and INCLUSION

DESCRIPTION (provided by applicant): The Clinical Protocol and Data Management (CPDM) function at The University of Kansas Cancer Center (KUCC) resides within the Clinical Trials Office (CTO). The CTO, led by Tara Lin, MD (CTO Medical Director) and Natalie Streeter (Assistant Vice Chancellor and Chief Operating Officer, Clinical Research, Strategy and Operations) under the direction of Weijing Sun, MD, FACP (AD for Clinical Research), provides comprehensive support services that span the life cycle of cancer clinical trials from concept through manuscript. The CTO provides centralized protocol management and reporting, with strong emphasis on data integrity, protocol compliance, education and training of CTO staff and investigators, and timelines for rapid trial submission and activation. The CTO supports KUCC investigators through the Disease Working Groups (DWG) to develop research portfolios that meet the needs of our catchment area. Enhancements to CTO operations enabled the growth of clinical research, with particular focus on investigator-initiated trials (IITs), early phase clinical trials and trials for underserved and rural populations. Cancer Center Program Leaders are integrated into CTO committees including the Clinical

Research Steering Committee and IIT Steering Committee so that CTO functions best serve the needs of the individual programs and promote translation of KUCC science to the clinic. The CTO expansion and staff specialization has enabled a steady increase in clinical trial accrual. From 2016-2020, there were 13,575 accruals onto interventional, observational, and ancillary/correlative studies. Accrual to interventional treatment clinical trials increased by 61% since the last grant period (3,965 accruals in 2016-2020 verses 2,462 in 2011-2015). Accrual to NCTN protocols increased overall by 111% (1,581 accruals in 2016-2020; 750 from 2011-2015). Our achievements led to our recognition as an NCTN "High-Performing Site," and awards of an NCORP grant and CATCH UP 2020 supplement focused on rural and underserved populations. Our commitment to increase clinical trial outreach to local community sites and the Masonic Cancer Alliance (MCA, network across Kansas and Missouri) resulted in increased accruals by 62% since the last grant cycle (404 accruals in 2016-2020; 506 accruals in 2011-2015). The creation of a dedicated IIT team within the CTO and the IIT Steering Committee resulted in an increase in accruals to interventional treatment IITs by 151% since the prior grant cycle (1,645 accruals in 2016-2020; 656 in 2011-2015). In summary, the CTO has efficiently leveraged its resources to support the growth of clinical research at KUCC, with a particular emphasis on developing IITs and bringing innovative and impactful clinical trials to meet the needs of patients within our catchment area.

CRITIQUE: The Clinical Trials Office (CTO) at KUCC is where the CPDM resides. The CTO provides infrastructure to support cancer clinical research studies, oversight of cancer clinical research studies, and promotes diversity in clinical trial participants. It supports all trials in this consortium.

This is achieved through nine aims:
Aim 1: Provide a centralized infrastructure and support for all cancer clinical research conducted at KUCC.
Aim 2: Collaborate with KUCC members and COE in the translation of KUCC science to the clinic and the support of KUCC research priorities across the catchment area.
Aim 3: Promote translational research and provide comprehensive support services to KUCC investigators for IITs from protocol concept through publication.
Aim 4: Manage, coordinate and report on the conduct of cancer clinical trials including real-time metrics on clinical trials accruals, screen failures and protocol deviations.
Aim 5: Develop, assess, and refine processes to streamline the trial activation process to ensure the timely activation and completion of clinical research activities.
Aim 6: Expand and formalize clinical research education and training for investigators and staff.
Aim 7: Evaluate clinical trial accrual metrics and promote enrollment to clinical trials.
Aim 8: Manage and maintain center-wide data and safety monitoring functions under the comprehensive data safety monitoring plan.
Aim 9: Develop and implement strategies in collaboration with COE and the KUCC Catchment Area Committee to enhance clinical trial participation among women, minorities, the underserved and rural populations, and patients across the lifespan.
The CTO is led by Medical Director Tara Lin, MD, and Natalie Streeter, RN, MSN. These individuals oversee a process whereby the entire span of the clinical trial from conception to publication is achieved.

At the previous review, several deficiencies noted were not severe and the center has taken specific actions to correct all deficiencies. First, there was a criticism about both accrual and innovation of the clinical trials. The center set a steering committee in 2015 which was upgraded as a response to the critique to include a specific mission of careful oversight and mentoring of IITs in 2018. There was a $1

million input into IITs and also 55 IITs have been added to the portfolio since the time of the last critique this was due to establishment of a dedicated IIT team (2016-2020). A second critique involved the fact that not all trials appeared to be under the auspices of the CTO, this is clearly not the case now and every trial is under supervision of the office. Further, the third criticism was broader and perhaps more difficult to address. There was a question that trials were not offered throughout the entire network of clinical sites equitably and whether quality assurance and oversight metrics were in place to for appropriate monitoring. IN response, all clinical trials open at the network of practices and hospitals are under the direct oversight of the CTO. Further, staff are trained centrally by the CTO and follow all CTO SOPs. Adequate management has also been dedicated to focus exclusively on community practice staff. In response to concerns about the experience level of DSMC members and number of patients audited, additional senior investigators with experience as clinicians and principal investigators have been added to the DSMC and the number of cases selected for audit has been increased. There is an overlap function that helps to match clinical trials with specific portions of the catchment to ensure these patients are adequately served by the clinical trial portfolio at KUCC. Further, physicians from the community practice serve on Disease Working Groups (DWGs) to facilitate discussion on clinical trials selection for niche areas of the catchment. As one example of success, 486 patients were enrolled on interventional treatment trials at community sites from the time of the last review, this represents a 75% increase from the time of the prior review.

The CPDM functions at KUCC are executed through the CTO. The KUCC CTO provides centralized support for all cancer trials. The most recent component is to also oversee all the non-interventional trials as well as of 2019.The community cancer program includes clinicians who practice within four Kansas City community sites in Kansas and Missouri. Together, the ACP and CCC sites have 47 faculty, and the children’s hospital has 23 pediatric oncologists who serve as PIs. The CTO personnel increased from 91 FTEs to 160 FTEs over the past five years to serve to address the 9 Specific aims. The CTO supports all the DWGs as they vet research priorities, develop IITs, etc. The CTO is organized into Clinical Operations, Regulatory Affairs, Centralized Reporting, Training and Education, Site Development & Program Management, and IIT management. There are three partnering institutional units namely investigational pharmacy, finance, and correlative lab. The relationship between the finance unit and the Cancer Center will need to be clarified. The Cancer Center Director, Dr. Roy Jensen is the ultimate report in this system. Many of these functions seem to have been delineated between 2015 and 2018. Further, in 2020 there was another reorganization to align better with the systems clinical research priorities. This has been 80% expansion in FTEs from the time of the last renewal as well as adding considerable, but necessary, complexity to a center that is striving to serve the needs and outreach of the center in translating science into the catchment area. Important changes include creation of an IIT steering committee to mentor junior faculty in the development of IIT concepts, >$1 million in funding for IIT over the last five years, and direct CTO oversight of clinical trials at network sites. The CTO services have expanded into the management off interventional non treatment cancer related trials studying in 2019. Some more details of how the interventional non treatment trials are currently coordinated would be useful.

To improve study startup timelines, direction of all studies startup activities transitioned out of clinical operations to a dedicated site development and project management team that was created in 2016. The team supports DWG's, pursues new trial opportunities, and coordinates study startup activities. The team also facilitates strategic partnerships with industry sponsors as they visit KUCC. Site development team members meet with DWG chairs, attend DWG meetings and field inquiries from investigators, and track metrics regarding potential trials pursued versus declined at the pre-DWG, DWG, and ERC levels. The site development team uses the clinical outcomes database (C3OD) for

real time patient accrual estimates to facilitate study feasibility assessments. The database pulls data from multiple sources including EHR, to my registry, biospecimen shared resource, to find the number of patients matching study eligibility. There is also an early phase clinical research unit which partners with the drug discovery and development steering committee (D3SC) as well as the investigator-initiated trial steering committee (IITSC) to conduct translational investigations. The unit conducts studies requiring complex pharmacokinetic studies, and high-quality tissue samples. This an important recent development and how this partnership occurs to improve the pipeline into IITs is still in early development and not completely clear. While the CPDM investigators have provided more detailed information about their audit process, they have not fully addressed how the resolution of corrective actions is being documented. Continued work is required to reach all segments of the KUCC catchment area, particularly as the number of IITs increases. Active oversight of enrollment activities by the Site Development team will help ensure the trial portfolio meets the needs of the catchment area, and appropriate metrics are being captured.

Accruals have improved over the past five years for virtually all types of trials. The CTO expansion and staff specialization has enabled a steady increase in clinical trial accrual. With regard to interventional treatment trials for the system, accruals are increased by 68% from 2152 from 2012-2016) to 3618 (2017-2021). There were significant increases for NCTN clinical trials, institutional, and industry trials. There is a stability or increased accrual for all sub types of trials, with the exception of “externally peer reviewed trials”. For all interventional trials there was some fall in accrual secondary to covid but there is an explanation and mitigation plan in the document for this reality. There were 13,575 subjects accrued to trials of all types under the new umbrella of the CTO including the main campus and all ancillary consortium sites. A information supplied at the site visit demonstrated that from 2016-2020, all types of trials had a shortened mean time to activation that Dr. Lin stated is approximately 4.5 months at the site visit. The median times are shorter. The pharmaceutical industry trials are longest. Dr. Lin has established an executive committee, the excellence in activation (EIA) task force to enhance this startup process. This team essentially places all trials on critical pathways to examine for efficiencies in activation, which is quite innovative. Quality assurance/improvement metrics for the various trial types, advancement of science and clinical protocols into the catchment, and how conflicts are managed at various levels of protocol review appear to be in place. As a result of these achievements, KUCC was recognized as an NCTN “High-Performing Site” and NCORP and CATCH UP supplemental grants were awarded focused on rural and underserved populations. Since this operation has been greatly expanded in the current funding period, definitive conclusions on the overall success of this entire enterprise will be readily apparent in future.

Personnel: Tara Lin, MD – Medical Director (1.2 CYM total effort) was appointed Medical Director of the Clinical Trials Office of the University of Kansas Cancer Center in July 2017. Dr Lin performed her oncology fellowship at Johns Hopkins, and in addition to her MD degree, she also holds a master’s degree in clinical research. She has been the local PI of more than 20 clinical trials and is a member and former co-chair of the Leukemia/Myeloid Disease Working Group. She was a member of the KUCC DSMC from 2011-2017. She was selected to join the Clinical Research Innovation Committee of the AACI in 2018. She is also active member of the SWOG Leukemia Committee since 2011. She is well qualified for this role at the center.

Natalie Streeter – (3.0 CYM total effort) has over 21 years of experience in the oncology clinical research field, and expertise in managing oncology projects. She joined KUCC in 2018 as the Executive Director of Clinical Research, Strategy and Operations and is now Assistant Vice Chancellor

and Chief Operating Office for Clinical Research, Strategy and Operations. She is well qualified for this role at the center.

Autumn Tribitt – Clinical Systems Program Manager (3.0 CYM total effort) has worked in clinical research since 2006, and specifically in the field of oncology clinical research since 2016. She is well qualified for this role at the center.

In summary, the CDPM continues to grow and adapt to the needs of the KUCC cancer clinical trials programs. the Clinical Protocol and Data Management has several strengths, with only minor weaknesses. The organizational structure and functions are comprehensive and well-coordinated. The quality control functions, and training services appear to be adequate. There are adequate plans in place to identify impediments to successful accrual of patients. Overall, the accrual to clinical trials both interventional and non-interventional is reasonable and increasing. Minor weaknesses include clarification of the roles of some committees, inconsistencies in the grant application on accrual numbers, and opportunity to enhance timely initiation of clinical trials. Future plans and directions are well-articulated and address the anticipated increases in complexity and needs over the next five years.

Assessment: Outstanding merit

Budget: The budget is appropriate as requested.

Protections for Human Subjects

Data and Safety Monitoring Plan

CRITIQUE: The Data and Safety Monitoring Plan (DSMP) at KUCC has undergone changes, notably including a significant revision in 2020 as indicated in the application. These changes were subsequently approved by NCI in April 2021. There is a single DSMP that oversees all trials at KUCC and its consortium partner, Children's Mercy. This DSM plan encompasses all human subject research conducted at KUCC and at Children's Mercy Kansas City.

The broad scope of this plan includes Investigator Initiated Trials conducted at both institutions of the following type: treatment, preventative care, supportive care, and diagnostic. A well-defined process across all clinical trials requires auditing commensurate with the degree of risk involved in study subject participation, and accounts for the size and complexity of the study. The KUCC DSMC has the authority to require protocol amendments, suspend, or terminate any research activities that fall within its jurisdiction, and can institute other appropriate actions as needed to protect participant safety.

Oversight of all studies appears to be structured in a way that allows for intervention when appropriate and incorporates proper organizational reporting in place across the entire study portfolio. Leadership is poised to adapt DSMP to recruit expert medical monitors by continuing to evaluate its portfolio of investigator-initiated trials to identify those that may require additional oversight by allowing the nature of the trial to determine specific needs to maintain trial integrity and patient safety.

Concerns at the previous site visit regarding predominance of junior faculty committee membership have been addressed with the addition of new appointments of more senior faculty to the DSMC.

Assessment: Acceptable

Budget: The budget is appropriate as requested.

Inclusion of Women in Clinical Research: The proportion of women who comprise KUCC cases (49%) is similar to catchment area (50.5%), slightly higher among treated patients (53%), and higher for interventional (55.7%). Plans for improving recruitment of women include the appointment of Dr. Chen as AD for Health Equity, the Masonic Cancer Alliance which expands the network of state and regional hospitals, development of the PIVOT program to provide patient insights into ongoing research, selection as an NCORP site with a focus on rural populations, and various community events by the CPC program to address barriers to research participation by minority communities. In charts inclusive of all years for which this competing grant is submitted, women represent 58% of those accrued to interventional treatment trials. In interventional non-treatment trials, accrual rate is similar at 57%. There were 1475 patients accrued to observational trials with women representing 78% (n=1149). Accrual of women to clinical trials remains consistently strong.

Assessment: Acceptable

Inclusion of Minorities in Clinical Research: The KUCC catchment area is ethnically diverse with 12.1% racial minorities, 10.3% Hispanic, and includes a significant area of rural patients representing about 25% of the population of the CA. Cancer incidence for minority populations is well-defined. The cancer cases in Black/African American communities are 7% and closely mirrors the demographic area (8%). American Indian/Alaska Native, Asian, Native Hawaiian/Pacific Islander each have cancer incidence rates at least 50% lower than their numbers in the population. While ~10% of the population is Hispanic/Latino, the cancer incidence in this group is just under 3%. Similarly, rural population accounts for 23% of the catchment area with a cancer incidence rate of 12%.

Accrual to interventional treatment trials is representative of the cancer incidence across most minority groups. Similar accrual representation is noted across interventional non-treatment and observational/ancillary trials. Of note, accrual of Black/African Americans to all trials is highly impressive and well above CA cancer incidence in this demographic. With a cancer incidence rate of 7% among Black/African Americans, KUCC has representation in interventional treatment trials at 24%, and this group is represented at 10% of interventional non-treatment trial accruals, and 12% of observational/ancillary accruals trials.

KUCC is commended for accrual to interventional treatment trials in rural communities. Cancer incidence among rural patients is 12%. Rural patients represent 11% of accruals to interventional treatment trials. Building on the strong partnerships, particularly with MCA, KUCC's ongoing efforts to identify opportunities to increase rural accrual to interventional non-treatment and observational/ancillary trials as appropriate.

There are continuing efforts for monitoring and improving recruitment of minorities. These efforts are led by Dr. Ronald Chen, who was appointed as Associate Director for Health Equity in 2019. Examples include the monthly Masonic Cancer Alliance DWG via interactive video with physicians located at the distant MCA sites. This DWG reviews the full portfolio of studies available to their participants and identifies catchment area needs. Enrollments onto interventional treatment trials at the MCA sites have increased from 127 (2011-2015) to 167 (2016-2020).

The 2019 selection of KUCC as an NCI MU NCORP Site and the subsequent CATCH UP-2020 grant is having a positive impact on accruals across all minority populations. The impact is already observed in 2020 with 183 patients accrued to NCORP trials and 44 accrued through the CATCH-UP grant and 54% of these patients were from rural/underserved populations. A Cancer Care Delivery and Health Equity DWG (CCDHE) was established in 2019 that could further enhance minority participation on clinical trials.

At the prior review, concerns were raised about those who are counted as “other,” specifically in the racial categories. It is noted that the largest percentage of “other” across all the three trial categories is observed in observational/ancillary studies. The KUCC has listed two separate categories. One is “other” and the second is “Unknown or Not Reported.” The highest percentage is no longer simply listed as “other,” but has been further sub-divided to included “unknown/not reported.” While the percentage in the latter category is high at 28%, it is worth noting that studies of this nature may allow participants to opt out of sharing their race/ethnicity.

In addition, at the prior review, concerns were raised about low Hispanic participation given estimates of anticipated growth in this minority population. The KUCC accrual to all trials across the Hispanic population has kept pace with cancer incidence in the current review cycle and they are recognized for maintaining their commitment to monitor cancer rate in Hispanics.

Overall, the proportion of minorities to interventional treatment and interventional non-treatment trials are almost proportional to the demographics of the catchment area, and to the patients seen in the cancer center and its network. There are appropriate plans among the programs at KUCC and across community partnerships for monitoring, retaining, and improving recruitment of minorities.

Assessment: Acceptable

Inclusion of Individuals Across the Lifespan in Clinical Research: Pediatric Oncology is now an expanded component of KUCC with more formalized arrangements with Children’s mercy from the time of the last review. The hospital is located a few minutes’ drive from the main campus and Pediatric Hematology/Oncology faculty are members of the center. There has been considerable academic expansion on the campus as well. The KUCC catchment area demographics indicate 27% pediatric (0-18 years), 16% elderly (65 and older), and 57% in the 19-64 age group. As expected, the cancer incidence rate for pediatrics is low at 1% and is highest in the elderly representing 56% of the catchment are cancer incidences. The percentage of pediatric patients treated at KUCC is 3% owing to the partnership between the center and Children’s Mercy. The accrual to pediatric trials matches or exceeds the incidence rate, and the percentage of pediatric patients treated at KUCC in this population. There is a strategy to enhance accrual under way in addition to the current status of pediatric cancer treatment accruals.

There is a difference between the cancer incidence rate and the patients treated at KUCC among the elderly. Charts show approximately 45% of elderly patients treated at KUCC which is 11% below the incidence rate age distribution across all cancer types. This is not insignificant and may be an area worth exploring to determine if there might be ways to better reach and treat the elderly population. In addition, in the elderly population, accrual to all trial types is below the incidence rate, and also below the rate of elderly patients treated at KUCC. 34% of elderly patients are accrued to interventional treatment trials, 12% accrued to observational trials while 44% (closely mirroring the percentage of elderly patients treated at KUCC) are accrued to interventional non-treatment trials. It is worth noting

this population may not meet eligibility criteria for participation owing to underlying health conditions and other mitigating factors. During the site visit it was indicated that KUCC is actively seeking a geriatric oncologist which strengthens commitment to serving the needs of the entire catchment area. Importantly, there is a section on accrual strategy of especially older patients in the document and this is logical and well described.

Assessment: Acceptable

PROTOCOL REVIEW AND MONITORING SYSTEM

DESCRIPTION (provided by applicant): The Protocol Review and Monitoring System (PRMS) oversees and ensures the scientific merit, appropriate resourcing, and progress of all cancer-related clinical studies at The University of Kansas Cancer Center (KUCC) and its consortium partners. PRMS evaluation occurs prior to submission to the Institutional Review Board (IRB), and does not overlap with its responsibilities. The PRMS has two stages of review: 1) the Disease Working Groups (DWG; report to the Associate Director (AD) for Clinical Research, Weijing Sun, MD, FACP; and the Executive Resourcing Committee (ERC; Tara Lin, MD, Chair, reports to AD for Clinical Research); and 2) the Protocol Review and Monitoring Committee (PRMC; Qamar Khan, MD, Chair, reports to the Deputy Director, Andrew Godwin, PhD). DWGs set priorities and portfolio needs, ERC evaluates feasibility and resources, and PRMC performs an independent scientific review. This two-stage process is formally recorded to maintain prompt activation of high priority studies and aligns with the CCSG guidelines. The PRMS process is aligned to ensure protocols receive high-quality peer-review and monitoring, and the research portfolio is consistent with KUCC clinical research priorities and catchment area needs. The 16 DWGs meet monthly for the initial review of scientific merit and available patient resources. The DWGs use a scoring system to prioritize studies, including disease specific needs. Highest priority is given to funded investigator-initiated, peer-reviewed trial proposals. DWG co-chairs are appointed by the AD for Clinical Research. Although the DWG composition is rich in clinicians focused on treatment trials and primarily Drug Discovery, Delivery and Experimental Therapeutics program members, members of Cancer Prevention and Control and Cancer Biology are also part of the DWGs. DWGs are evaluated yearly by the AD for Clinical Research for proportion of trials that are IIT and/or national, quality, translational nature of interventional trials, trial accrual, and national meeting presentations and publications. This data is used to further support areas of need as well as allocate staffing resources to growing and productive teams. The ERC reviews trial feasibility and resource assessment, protocol resource requirements, and available funding. The CTO sends DWG/ERC approved studies to the PRMC for scientific review. The PRMC performs independent scientific and biostatistical reviews, and adequacy of the data safety monitoring. The PRMC also monitors active protocols at least annually for scientific progress and accruals and terminates studies as appropriate. In 2020, the PRMC reviewed 287 new studies, 259 were approved and 15 were tabled and nine disapproved. In 2020, the PRMC reviewed 403 ongoing studies, 49 were placed on probation and 15 were terminated. In August 2020, PRMS was integrated into the Velos eResearch Clinical Trial Management System resulting in improved tracking of the protocols, enhanced communication between the stages of protocol review and efficient collection of metrics on PRMS activities.

CRITIQUE: The protocol review and monitoring system (PRMS) at the University of Kansas Cancer Center (KUCC) oversees and ensures the scientific merit, prioritization, appropriate resourcing and progress of all clinical studies at KUCC and its consortium partners, predominantly Children's Mercy (CM). All clinical trials are supported by the Clinical Trials Office (CTO). KUCC has a well-defined two stage review process with the first stage occurring in the Disease Working Groups (DWGs) and the

Executive Resourcing Committee (ERC) and the second stage occurring with the Protocol Review and Monitoring Committee (PRMC). The PRMS leadership includes the PRMC chair, Dr. Qamar Kahn a medical oncologist, the chair of the ERC, Dr. Tara Lin, and the Associate Director for Clinical Research, Dr. Weijing Sun. The PRMS has continued to evolve and mature over the past 10 years with substantive improvements made at each stage. With initial cancer center designation in 2012, the PRMS achieved a “conditional approval” and corrective actions were made that resulted in full approval with comments in August of 2016. With the competing renewal application in 2017, PRMS achieved an approval rating.

Overall, the KUCC has responded appropriately addressed the weaknesses from the previous review. 1) In response to a concern regarding clarity for the initial review process, KUCC is now tracking metrics of the DWGs and ERC activities using the Velos eCompliance electronic management system. This appears to have aided in the flow of proposals, 2) There was a concern regarding clarity for the involvement of the Chair and Co-Chair in selecting reviewers with adequate expertise for the review of clinical studies. In response, starting in 2018, the PRMC Chair personally reviews and approves assignments of reviewers for all protocols to ensure adequate expertise, 3) There was a significant concern regarding the ability of the Center Director to overrule PRMC decisions. In response, the PRMC charter was amended in 2018 stating explicitly that the Cancer Center Director is no longer able to overrule PRMC decisions, 4) There was concern regarding the lack of expertise in population sciences and epidemiology. In response, two senior members have been added to the PRMC from the cancer prevention program. In addition, the PRMC Chair can ask for ad hoc reviewers if the protocol review requires additional expertise, and 5) There was a need for greater attention to documentation of the checks and balances of the review process including prioritization and DWG approvals and conflicts of interest. In response, the DWGs have now prioritized clinical trials using an objective scoring system, which was first validated within key groups. This scoring algorithm has been incorporated into the Velos eCompliance system. DWG metrics of performance are being collected to ensure alignment with catchment area needs. In addition, the PRMC Chair reviews all new trials being submitted to ensure no conflicts of interest exist before assigning reviewers. Collectively, these responses and actions have been very responsive to the previous concerns.

First Stage of Review Process (DWGs and ERC): KUCC has 16 DWGs with 11 of these as disease-specific and 5 non-disease-specific but focused more broadly on clinical research to meet the needs of the patient population. The first stage of protocol and review occurs in the DWGs which assume the primary responsibility to maintain and optimize the trial portfolio including the decision of which trials are moved through to the PRMS. As of 2020, metrics of all DWG activities are recorded via the Velos (TRAX) system. The DWGs utilize a scoring metric as demonstrated in Table 2 of the write-up. The scores are then reviewed by the DWG co-chairs, discussed at the DWG meetings, and used to prioritize approval of clinical trials. There is a concern that the scoring metric does not include how minority and underrepresented patients from the catchment area are considered and whether priority is given for trials that focus on these populations. There is also some concern regarding the overall rigor of the process since, as noted in Table 3 showing DWG metrics for 2020, less than 10% of the protocols are disapproved at the DWG level. One would expect that this initial review group would disapprove a greater percentage of protocols at this stage. The second part of the initial review process includes assessment by the ERC which provides an independent review of all DWG protocols to ensure adequate resources are available and that allocation of CTO resources are aligned with cancer center priorities. As noted above, the ERC is chaired by Dr. Tara Lin, who is the medical director for the Clinical Trials Office and Director of the Acute Leukemia Program. The membership of this committee

appears appropriate. In addition, there appears to be adequate support for the DWGs and the communication strategy for the DWGs and the PRMC is appropriately discussed and outlined.

Second Stage Review (PRMC): As noted above, the PRMC performs an independent review of the scientific merit and appropriateness of the statistical analyses to assess the adequacy of the data safety monitoring that is being conducted by KUCC and its consortium partner, CM. The PRMC has the sole authority to open protocols that meet rigorous standards and terminate protocols that fail to meet accrual goals or are unable to maintain scientific progress. The PRMC is chaired by Dr. Qamar Kahn, who is a professor and medical oncologist with expertise in conducting IITs in breast cancer. In his role as PRMC Chair, as clarified at site visit, Dr. Kahn reports directly to the AD for Clinical Research, Dr. Sun (this however does not correlate with the PRMS write-up stating that Dr. Khan reports to the deputy director, Dr. Godwin). To facilitate reviews, the PRMC is organized into 2 subcommittees with Subcommittee A meeting on the second Thursday of the month and Subcommittee B meeting on the 4th Tuesday of the month. There is a bit of confusion regarding how many members actually serve on the PRMC. It is initially stated that the PRMC consists of 31 members, however in the description of the two subcommittees it was noted that Subcommittee A has 18 members and Subcommittee B has 17 members. During site visit, it was clarified that the PRMC has 35 members (not 31). A minimum of 75% voting members of each committee must be present for the meeting and vote as this constitutes the quorum. Of note, meetings have never been cancelled due to lack of quorum. If a member of the committee has a conflict of interest, the member is asked to leave the room during the voting process, and this is documented in the minutes from the meeting. PRMC recommendations are sent to the PI and study contact the day after the meeting unless additional review and discussion is required. Overall, there is good representation of all requisite disciplines on each subcommittee and the conflicts of interest are clearly delineated as are the review criteria. Metrics clearly delineating the time to activation for various study types was provided at site visit in response to questions. There is a persistent concern once again regarding overall rigor of the initial and second stages of review. As noted above, less than 10% of all protocols were disapproved at the DWG level and reviewing the metrics for the PRMC decisions in 2020, less than 5% of protocols were disapproved at this stage, which is consistent with the prior years as well. It does appear, however, that with the PRMC annual reviews, 15 of the 403 protocols were terminated in 2020 and 49 were placed on probation. Overall, except for the concerns noted above, it appears that the PRMC is continuing to fulfill its role in accrual monitoring and authority to close underperforming studies.

Six protocols were submitted by KUCC for review prior to the site visit to ensure alignment with the center's stated PRMS processes. Review of these six protocols demonstrates appropriate quality control and processes in place. Overall, review of these protocols supports that the PRMC is doing an adequate review and the contributions of reviewers are appropriately documented. In addition, the center has appropriate distinction of the separate roles of the PRMS and the IRB processes. No cancer/cancer-related study is considered by IRB without prior PRMC clearance. There is appropriate administrative support for the activities for both the DWGs and the PRMC.

In summary, KUCC has been responsive to past critiques and the PRMS continues to mature and serve the center well. There is a clearly defined two-step review process which is fundamentally adequate and responsive to CCSG guidelines. The leadership of the PRMS and membership of the various components are adequate with mechanisms in place to ensure an appropriate quorum. In addition to the positive response with regards to the 2017 review, the Velos eCompliance management system has been instituted as of 2020 to assist with collection of performance metrics. This platform also helps to streamline the submission and review processes and allows the study team members to

electronically submit all the study documents and applications which greatly expedites the review process. Areas of concern that will require additional focus include: 1) a better assessment of the rigor of the review process. Notably, there is an expectation that the DWGs should be disapproving at least 30-40% of the initial protocols. This was partially addressed at site by noting that some protocols are rejected by the DWG leader prior to it coming to the committee; however, these metrics should be collected and reported in an objective fashion, 2) the write-up states that the DWGs can terminate active trials; however, during discussion at site visit, it seemed like this was not the case and that the PRMC has this capacity, and 3) time to activation for most trials still require work to further improve.

Personnel: Qamar J. Khan, MD – Chair (1.2 CYM total effort) is professor of medicine at the University of Kansas School of Medicine since 2005 and a breast cancer oncologist. He has developed several IITs as the principal reason for his directorship of this entity. Dr. Khan is well qualified for this position.

Ms. Morgan Steffes – PRMS Coordinator (2.4 CYM total effort) has three years of experience in internal administration focused within the financial services industry. She has worked in compliance specifically in a variety of roles. She is well qualified for this role.

Assessment: Satisfactory

Budget: The budget is appropriate as requested.

DEVELOPMENTAL FUNDS

DESCRIPTION (provided by applicant): The University of Kansas Cancer Center (KUCC) requests Cancer Center Support Grant (CCSG) Developmental Funds to support pilot research projects, supplement new faculty recruitment packages, and support Clinical and Special Populations Staff Investigators to promote translational and clinical science research activities and help extend those research activities to underrepresented populations. Funding pilot projects, recruiting new faculty, and supporting Staff Investigators will collectively enrich research endeavors towards strategic priorities, enhance the ability of KUCC to serve the Cancer Center's catchment area, and importantly help mitigate the impact of cancer in our region as well as nationally. KUCC leadership believes that activities supported by CCSG Developmental Funds will enable KUCC to provide a rich environment to develop paradigm-changing therapeutics and interventions, and thereby enable the funding of multi- and transdisciplinary team-based grants. These funds will allow us to focus the power of precision medicine, basic science inquiry, drug discovery and development, and behavioral interventions to decrease cancer incidence, morbidity, and mortality. Furthermore, Developmental Funds will help KUCC promote a Cancer Center culture that supports our highest priority of leveraging the collective state-of-the-art basic, clinical, translational and population research programs to understand cancer at a fundamental level and catalyze a comprehensive, multidisciplinary approach to improve patient outcomes. KUCC has demonstrated a successful track record in its investment of CCSG Developmental Funds and other KUCC-directed funding mechanisms since receiving NCI designation in 2012 and will continue to grow a strong return on investment from these funds.

CRITIQUE: Cancer Center Support Grant (CCSG) Developmental Funds have been used during the current funding period (2016-2020) to invest in: 1) strategic, high-impact research projects; 2) developing shared resources; 3) new faculty recruits; and 4) a clinical staff scientist to support the KUCC vision, goals and aims. In the proposed funding period, The University of Kansas Cancer Center (KUCC) requests CCSG Developmental Funds to support: 1) pilot research projects; 2) new faculty

recruits; and 3) clinical and special populations Staff Investigators. Developmental Funds offer tremendous flexibility to leverage additional KUCC and institutional funds for research projects and faculty recruits and drive strategic KUCC initiatives.

The current project period has successfully invested in 24 pilot projects totaling $779,626 with a ROI of $6,956,736 in extramural funding and 69 peer-reviewed publications. In addition to CCSG funds the institution committed an additional $800,056 for 27 awards returning $10,023,914 in extramural funds and 30 additional peer-reviewed articles. In aggregate this represents a substantial increase in ROI from the prior period, 6.3 compared to 10.7. These awards are evenly distributed across the three programs, CB- 19, CPC- 17, and D3ET- 15. KUCC used a combination of institutional and external funding to support 41 faculty recruitments during this time. Though noted that developing resources are no longer applicable under the new PAR and have instead moved to the Shared Resource Management component, KUCC invested previously in three developing resources, two of which are no longer active: Health Communications Research and Cell Authentication and Pathogen Screening Shared Resource. One shared resource has been included in the most recent application, Nutrition Shared Resource (NSR) as a full SR in the SRM component. It is commendable that the two now defunct services were properly evaluated and sunset via a thorough review process. Likewise, the continuation of the NSR is an asset to a wide spectrum of faculty researchers with use by over 60 KUCC members. KUCC supported Dr. McGuirk as a clinical staff scientist since 2017. Dr. McGuirk has established a successful CAR T program with 22 active trials and treatment of more than 120 patients. His involvement with basic scientists in the CB and D3ET programs supports the interdisciplinary strategic aims of the Center. Several nascent projects show promise including a collaboration with Goodwin on Ewing sarcoma and work on new CAR T strategies in GBMs.

The KUCC has made extensive progress addressing the critiques in the prior summary statement. Associate Directors and programs leaders are more involved throughout the life cycle of the awards process, helping craft RFAs that align more closely with the Center's "Road to Comprehensiveness" and other strategic initiatives. In addition, they form the core of a stable group of reviewers for submitted proposals. However, limited details are provided on how the leadership team decides on RFA language and intent. An increased focus on promoting MPI grants and other larger mechanism awards has been successful with one funding COBRE and four teams that are developing P01 submissions. MPI grants have increased from 42 to 60 during this funding period, an appreciable increase. However, only two appear to have originated from the development funds.

The review process as described is robust and is established to provide consistent reviews that align with the objectives of the Center. The selection criteria include questions that promote interdisciplinary collaboration, thematic compatibility, and impact on catchment area, among other criteria. The inclusion of a patient advocate through PIVOT on the review panel is well deserved and an important intersection with Community Outreach and Engagement. Administrative support for the Development funds is acceptable. Further consideration in this next cycle should be given to integration of PED and the Development funds components.

KUCC proposes to increase pilot award funding from $35,000 to $50,000 due to general cost increases as well as way to encourage additional team science applications, a reasonable request. Furthermore, they outline several key areas of faculty recruitment for the future cycle. These recruitment areas in Neuro-Oncology, Molecular Cancer Epidemiology, Cardio-oncology, Genetics, Surgical Oncology, and Immunology are aligned with the strategic plan and support all three programs.

It is apparent that the development funds support the general KUCC mission however, there exists additional opportunities to use development funds to better catalyze and promote the strategic aims and initiatives. Two multi-investigator awards were noted at the Site Visit as originating from this component. This was considered low relative to the overall objectives and output of the Center with regards to collaborative efforts.

Assessment: Outstanding merit

Staff Investigators

CRITIQUE: Salary support for two staff investigators, Drs. Joaqunia Baranda and Elizabeth Calhoun are requested. Dr. Baranda's prior work is well-documented, and her successes are apparent. Of note is her work on acquiring a CCSG supplement (CATCH-UP 2020) that is focused on improving access to care for underserved populations, which has already seen positive success. Her role as Director of the Early Phase Program and Co-Chair of the Investigator Initiated Steering Committee will also prove helpful in expanding the KUCC clinical base. Dr. Calhoun is a nationally recognized leader for minority health and health disparities and Associate Dean for Population Sciences. Her publication and grant record in this field is robust and she will likely contribute to the expansion of access and outreach to the catchment.

Assessment: Acceptable

Budget: The budget is appropriate as requested.

LEADERSHIP, PLANNING AND EVALUATION

DESCRIPTION (provided by applicant): Roy A. Jensen, MD, serves as the Vice Chancellor and Director of The University of Kansas Cancer Center (KUCC). Jensen has assembled an experienced and nationally recognized team of leaders in basic science, cancer prevention and control, translation science, health equity, clinical care, and education to help him actuate the vision to establish KUCC as a world-class cancer center that is at the forefront of discovery, development and implementation of knowledge, technology and novel therapeutic agents for the treatment and prevention of cancer. Jensen's Senior Leadership team includes Andrew K. Godwin, PhD (Deputy Director), Shrikant Anant, PhD (Associate Director for Basic Science), Christie Befort, PhD (Associate Director for Cancer Prevention and Control), Ronald Chen, MD, MPH (Associate Director for Health Equity), Teresa Christenson, ASA (Assistant Vice Chancellor and Associate Director for Administration), Matthew Mayo, PhD, MBA, FASA (Associate Director for Shared Resources), Weijing Sun, MD, FACP (Associate Director for Clinical Research), Scott Weir, PharmD, PhD (Associate Director for Translational Research), and Danny Welch, PhD (Associate Director for Education). This Senior Leadership team constitutes the Associate Director's Council and works together to foster collaborative initiatives across disciplines and campuses, define areas of strength, address areas of weakness, and integrate basic scientists and clinicians for both the advancement of basic discoveries and training and education efforts. Jensen and his Senior Leadership team join research program leaders, communication leaders and health system leadership to form the Leadership Council. The Leadership Council ensures all parties are aware of and integrated into KUCC strategic initiatives that will help KUCC achieve its goals and aims. The KUCC External Advisory Board (EAB) provides objective review and critical guidance for the research programs, administration, shared resources, and clinical research infrastructure. Both internal and external planning and evaluation activities are an essential component

of KUCC's continued and steady improvement over the past grant period (2016-2020) and will continue to play an essential role in the future. Overall, Jensen and the KUCC Senior Leadership team have effectively utilized the Cancer Center Support Grant to put in place a vigorous and robust process of vision setting, evaluation of progress, implementation of improvements, and planning for the future.

CRITIQUE: Dr. Roy Jensen has been the KUCC director since 2004 and was named Vice-Chancellor of the Cancer Center in 2021. He also is the William R. Jewell, MD Distinguished Kansas Masonic Professor, the Director of the Kansas Masonic Cancer Research Institute, Professor of Pathology and Laboratory Medicine, and Professor of Cancer Biology. Jensen served as the chair of the NCI Cancer Centers Subcommittee A and as President of the Association of American Cancer Institutes.

Under his guidance, the center has achieved and maintained NCI designation for the past decade. He has assembled an effective senior leadership team, is responsible for all programmatic and fiscal management of the KUCC across the consortium and has final decision-making power. He reports directly to the Executive Vice-Chancellor of the University of Kansas Health System and the Provost and Executive Vice-Chancellor of the University of Kansas-Lawrence. He has developed exceptionally effective communication channels to the CEOs of the Stowers Institute for Medical Research and Children's Mercy with regular meetings, collaborations, and updates.

Dr. Godwin was appointed Deputy Director (DD) reporting to Dr. Jensen of the KUCC in 2013. He holds the Chancellor's Distinguished Chair in Biomedical Sciences and is the Division Director of Genomic Diagnostics at KUMC. Nationally, Godwin is the Vice-Chair of the Breast Translational Medicine subcommittee of SWOG (since 2019) and was appointed to the NCI's NCTN Core Correlative Sciences Committee in 2021. He is a well-respected translational researcher who is internationally recognized for his work in elucidating the genetic basis of GIST and ovarian and breast cancer. In his role as DD, he oversees the Pilot Project Program; the Quality Assurance (QA) program for clinical trials; the Data and Safety Monitoring Committee (DSMC); the Personalized Cancer Medicine Initiative, including directing Biomarker Discovery; the Laboratory to support correlative research for clinical trials; he coordinates research activities of the divisions of Medical Oncology, Surgical Oncology, Radiation Oncology, and Gynecological Oncology; as well as assisting the Director and the AD for Administration in managing the KUCC budget, including the funds to support investigator-initiated clinical trials. He has served effectively in his role as DD.

Dr. Shrikant Anant has been the AD for Basic Science since 2018 and from 2010-2018 served as AD for Cancer Prevention and Control. His research involves understanding the molecular mechanisms of tumorigenesis and the resistance of cancer cells to treatment. He has focused part of his research effort on identifying and characterizing the role of cancer stem cells in tumorigenesis and determining the mechanisms of action for various natural products in cancer prevention. In his role as AD, he oversees strategic basic science recruits for the Cancer Biology research program; monitors progress towards the program's future goals; establishes, fosters, and catalyzes connections between basic scientists at the four main campuses; assists KUCC members in identifying collaborations to enhance basic science translational initiatives; and collaborates with the AD for Education to drive the formation of multidisciplinary teams that would effectively compete for multi-PI grants, SPORES, and program project grants. He has served KUCC effectively.

Dr. Christie Befort has been the AD for Cancer Prevention and Control since 2018. From 2016 to 2018, she served as co-leader of the former Cancer Control and Population Health research program. She is a Professor of Population Health and has a keen interest in behavioral weight control interventions to

improve cancer prevention, survivorship, and quality of life. In her role as AD, she helps recruit new faculty for the Cancer Prevention and Control research program; monitors progress towards CPC future goals; identifies CPC needs for new shared resources; collaborates with the AD for Health Equity to integrate outreach and research efforts across the entire catchment area and leverages her experience with underserved rural populations and provides advice and guidance to KUCC members relative to cancer prevention and control activities. She also helps encourage intra- and inter-programmatic interactions and multidiscipline, multi-investigator cancer prevention, and cancer control-focused grant applications. She seems effective in her role.

Dr. Ronald Chen has served as the AD for Health Equity since 2019 and is the Brandmeyer Professor and Chair of Radiation Oncology. He specializes in treating prostate and bladder cancers and helps to guide some of the National Standards in the GU field. Chen has a well-funded research program focused on cancer disparities, cancer care delivery, and comparative effectiveness. He has extensive experience collaborating with stakeholders on local and national levels to inform his research and use population-based data to examine cancer burden. In his role as AD, he develops overarching strategies to increase enrollment of underserved populations into clinical trials, including clinical, non-clinical, and survivorship trials, and coordinate efforts across programs to increase recruitment of underrepresented populations into cancer research efforts more broadly; utilize the Community Advisory Board, PIVOT members, and OPTIK to inform research Program Leaders regarding catchment area priorities to assist their program members in identifying, implementing and funding research that is critical to reducing cancer-related health disparities; work across the full spectrum of translational cancer research to ensure that health disparities are addressed at the levels of basic discovery, clinical trials, and community engagement. He works directly with community members, particularly the rural, African American, Native American, and Hispanic communities, to address their interests and needs. He also helps identify barriers to minority participation in clinical trials, develops targeted interventions to reduce cancer disparities, evaluates the effectiveness of such interventions, provides public policy leadership to mitigate the impact of cancer in the catchment area with a focus on tobacco prevention and obesity; develops partnerships with safety net clinics (KU affiliates and others) and K-12 schools to increase preventive screenings and vaccination rates, serves as the connection for health promotion between KU Medical Center and the Unified Government of Wyandotte County; and implements educational programs specific to the unique needs of the KUCC catchment area. He has made progress in all of these areas since the previous review.

Ms. Teresa Christenson serves as Assoc Vice-Chancellor and AD for Administration (since 2006). Her skills in project management, budget management, business, and process improvement are outstanding and have allowed for the continued growth of KUCC's faculty, staff, and shared resources. She plans, directs, monitors, coordinates, organizes, and evaluates all administrative operations/activities; establishes CCSG application metrics and timelines. In collaboration with research program leaders, shared resource directors, and clinical leadership, prepares sections and attachments for the P30 CCSG; manages the strategic planning process; manages all KUCC fiscal activities such as the annual budget process, analysis of income and expenditures, projections for yearly budget requests and budgetary reports; coordinates and guides the integration of KUCC shared resources, monitors budgets, personnel, and organizational structure; oversees human resource activities for KUCC, assures that all personnel policies and procedures set forth by KUCC and KU SOM follow university policies, and she administers research grants awarded to members of the Cancer Center. She has been highly effective in her administrative role.

Dr. Matthew Mayo served as AD for Shared Resources since 2008 and is the founding Chair and Professor in the Biostatistics and Data Science department. His collaborative research interests include cancer prevention, exercise, and obesity. He guides each shared resources' scope, utilization, performance, and

cost-effectiveness; oversees the use of KUCC funds by reviewing annual budgets and business plans for each shared resource and makes recommendations to the KUCC Director, AD for Administration, and LC, including needs for new and replacement personnel, equipment, and space; advises on adherence to the CCSG guidelines for shared resources and development of the shared resource sections for the application; works with the shared resource Directors to establish an annual business plan and budget, charge-back system, metrics of utilization and performance, Internal and External Advisory Boards and yearly reports; conducts an annual review of shared resources and directors and provides recommendations to the Director; meets quarterly with each shared resource Director; bi-annually with all shared resource directors, and bi-annually with each KUCC program to identify needs for new shared resources and refinement to existing shared resources; serves as the KUCC central clearinghouse of information on shared resources and scope of services and works with Cancer Center Communications staff to facilitate a greater understanding of shared resources throughout KUCC membership.

Dr. Weijing Sun has served as AD of Clinical Research since 2017 and as Professor and Division Director of Medical Oncology. He also serves as the Institutional PI for the ECOG-ACRIN Cancer Research Group and is a Member of the GI Committee. As AD for clinical research he ensures KUCC has the necessary resources, infrastructure, Disease Working Groups, and types of interventional trials in cancer treatment, survivorship, and prevention in order to serve our catchment area; provides oversight of all clinical research infrastructure; interfaces with Dr. Tsue, KUCC Physician-in-Chief, to ensure that TUKHS facilities and service lines are well integrated with clinical research efforts; facilitates KUCC investigators connection and communication with national intergroups; coordinates national clinic research grant applications; serves as an advisor/resource to Cancer Center members about faculty areas of expertise and clinical research collaborations; provides guidance and advice regarding clinical research recruitment opportunities; participates on search committees; interviews candidates; reviews curriculum vitae and provides recommendations; reviews and provides recommendations on clinical and translational science seed grant applications; and helps facilitate and strengthen relationships with the pharmaceutical industry to enhance the Cancer Center’s clinical research portfolio and commercialization opportunities.

Dr. Scott Weir serves as AD for Translational Research since 2006 and has research interests in clinical pharmacology, pharmacokinetics/pharmacodynamics of anticancer agents, lead optimization, and early drug development strategies to achieve "fast into humans" translation. As AD of Translational Research enables, facilitates, and manages translation of laboratory discoveries into clinical trials; facilitates intra- and inter-programmatic interactions between basic, translational, and clinical researchers; develops ad hoc research working groups to promote new grant initiatives in translational research; advises KUCC Senior Leadership regarding the function and optimization of infrastructure needs to support translational research in close collaboration with Mayo (AD for Shared Resources); assists basic and clinical translational researchers to identify potential drug targets and validate drug targets; defines medicinal chemistry and lead optimization strategies, aligns project needs with LDO shared resource capabilities, and advances cancer experimental therapeutics to clinical proof-of-concept; leads efforts to establish collaborations and partnerships with industry, government, academia, and disease philanthropy partners to secure resources required to achieve bench-to-bedside translation; advocates for strategic recruits for the D3ET research program; and monitors progress towards D3ET future goals.

Dr. Danny Welch has served as AD of Education since 2018, and from 2011-2018 he served as AD of Basic Science. Welch is a Professor of Cancer Biology and is internationally recognized for establishing the Hallmarks of Cancer Metastasis. His research is focused on metastasis suppressors, and his laboratory has identified eight of them, including KISS1, BRMS1, TXNIP, CRSP3, ITIH5, HMP19, and two microRNAs. In his role as AD of Education, he provides leadership and strategic guidance to coordinate

and enhance cancer research education, training, and career development activities; assess current education activities, integrates them into programmatic efforts, and recommends new opportunities; coordinates education travel opportunities, seminars, workshops, and related activities; work closely with the community, outreach, and engagement committees to include special or underserved populations in cancer research education initiatives; organize the KUCC seminar series and ensures that seminars are devoted to timely cancer topics, and oversee the data derived from educational activities.

The leadership team has responded to previous weaknesses and carefully determined their course of action. The EAB also provided their feedback and advice, as well. Administration, senior leadership, research programs, shared resources, and the Clinical Trials Office (CTO) all undertook a high level of self-evaluation to determine the best path forward. Ultimately, Senior Leadership laid out eight strategic initiatives, referred to as ‘Road to Comprehensiveness,’ (see below) that carefully provided the roadmap to address all concerns. Dr. Jensen has been highly successful in maintaining a strong leadership team to assist him in carrying out the center’s mission.

Despite the prior recommendation to reconsider the number of Associate Directors (ADs) at KUCC, all six positions have been retained, and two more ADs have been added and the contribution of all of these individuals has been carefully explained. Their roles in the cancer center’s mission are now clear and justified. Multiple ADC (Associate Director’s Council) and LC (Leadership Council) meetings have been devoted to updates from section leaders of the strategic plan to monitor progress on implementing the vision and goals for the center. Since 2016, 41 researchers have been recruited or promoted with a total investment of over $47 million. All faculty recruitments are managed through a monthly recruiting committee meeting to help guide decisions to attain the best and brightest. Positions and final start-up packages, including space, equipment, and personnel, are approved by the ADC, the appropriate Department Chair, and Dean.

The Strategic Plan has been carefully refined and focused on the "road to comprehensive status." It includes very specific objectives to 1) obtain more multi-PI grants, 2) accrue 15% of patients into clinical trials, 3) address the geographic dispersion of the cancer center, 4) key recruitments to increase the overall impact of the science 5) Goal to submit three new INDs and accomplished five, 6) improve and enhance community outreach, expand, and improve the breadth/ depth of training. Individual teams were assigned to work on and track progress in each area to ensure that goals were being met.

The Senior Leadership Team has been strengthened in the current funding period, and tangible outcomes of its collaborative efforts are emerging and are making a real impact. The Cancer Prevention and Survivorship (CPS) and Cancer Control and Population Health (CCPH) research programs were combined into a single population sciences research program. They renamed the Cancer Prevention and Control (CPC) research, which was approved by the EAB 2019. The fifteen members of the EAB hold senior-level leadership positions, and their respective backgrounds and institutions make them well poised to serve on this committee. Together, the EAB has provided invaluable solid guidance to this center and is considered a major asset to the leadership structure, and their guidance is well considered.

In 2020, the administration created a project manager administrative position to work with each research program to set up and follow a research program annual plan and document research program meetings more carefully. A Catchment Area Steering Committee was formed and meets three times a year to analyze the catchment area, review catchment data, and continually evaluate how the research programs address the types of cancers prevalent and needs of the catchment population continuously assess the impact of KUCC on priority areas. A database was set up previously (OPTIK) that enables the KU Cancer

Center to prioritize action items for research and outreach and communicate the impact of those efforts more effectively.

Growth plans are clear and are focused on the continuation of the initiatives outlined in our strategic plan, such as 1) Build a new signature cancer research facility at KUMC that fosters transdisciplinary collaboration 2) Increase programmatic grants through strategic recruitments and targeted investment 3) Enhance training infrastructure through investments in trainee tracking, and strategies for further addressing the needs of the catchment area remain under development.

A careful study of the catchment area was undertaken, and strategies were developed to address the significant cancers in each research program. Leadership and planning have responded well to EAB guidance, and for example, KUCC leadership has seen substantial growth in multi-PI grants. In 2016, there were 42 multi-PI grants, and this has increased to 60 multi-PI grants in 2020; In 2019, Godwin and Soper were awarded an $11.5M Center of Biomedical Research Excellence grant (P20GM130423) to develop the “Kansas Institute for Precision Medicine”; In 2016 9% of KUCC patients were enrolled in interventional treatment clinical trials. And due to multiple initiatives of leadership, in 2019, this increased to 14.3% (with SARS-CoV-2 recruiting pause, accrual dropped to 11.6% in 2020); KUCC-MCA Rural MU NCORP was awarded in 2019 ($8.4M) and will assess institutional, provider, clinical trial, and patient barriers to trial accrual, and implement processes needed to correct problems.

Overall, the KUCC Director has impeccable credentials and a stellar level of accomplishment which he has skillfully used to achieve major growth and advances for KUCC. Other senior leaders are exquisitely qualified and accomplished. These strengths are slightly mitigated by high turnover. Planning is robust but the evaluation could be strengthened.

Budget: The budget is recommended as requested.

Assessment: Outstanding merit

Budget: The budget is appropriate as requested.

ADMINISTRATION

DESCRIPTION (provided by applicant): The University of Kansas Cancer Center (KUCC) administration office is the principal organizational component through which the Associate Directors, Research Program Leaders and Shared Resource Directors execute their responsibilities to Cancer Center members of a matrix consortium Cancer Center that includes: the University of Kansas Medical Center (KUMC) campus in Kansas City, the University of Kansas in Lawrence (KU-L) and via consortium agreement, the Stowers Institute for Medical Research (Stowers) and Children’s Mercy Kansas City (CM). In 2020, 171 members of KUCC accounted for $9.7M of NCI funding and a total of $57M in overall cancer-related funding, an increase of $8M since the last CCSG submission. These members span three research programs and are supported by seven full shared resources and one developing shared resource. The administrative office provides administrative and fiscal oversight of Cancer Center functions across four campuses. These functions include grant development, human resources, communications, Cancer Center Support Grant (CCSG) management, Cancer Center, Clinical Trials Office, and shared resource financial administration, outreach and information dissemination, and information technology. The KUCC administrative office is led by the Associate Vice Chancellor and Associate Director for Administration, Teresa J. Christenson, who reports directly to the

Cancer Center Vice Chancellor and Director, Roy Jensen. Christenson has organized the administrative office to efficiently facilitate and implement the Director's vision and support a cancer-focused culture that fosters collaboration and productivity among Cancer Center members. The aims of Administration are to: 1. Provide direction, leadership, and cost-effective management of resources for KUCC members across four campuses and with its consortium partners. 2. Establish, organize, and maintain consistent information and dissemination across research programs, shared resources, oversight committees and consortium partners to ensure Cancer Center aims are met. 3. Enhance research, clinical trial, and outreach opportunities for KUCC members by facilitating collaborative, cross-disciplinary collaborations across campuses and consortium partners.

CRITIQUE: The University of Kansas Cancer Center (KUCC) administration office is the principal organizational unit through which the Associate Directors, research program leaders, and shared resource directors execute their responsibilities to cancer center members. The KUCC administrative office is led by the Associate Vice Chancellor and Associate Director for Administration, Ms. Teresa J. Christenson, who reports directly to the Cancer Center Vice Chancellor and Director, Roy Jensen, MD. Ms. Susan Harp, MFA, serves as the Director for Grant Development & Research Resources has successfully provided pre-award support for 162 faculty who submitted over 1,000 grant applications, resulting in $108 million in funded research, and coordinates the pilot project program, which has been in place for 16 years resulting in over 250 awards. Additionally, Ms. Theresa Leinwetter has served as the Assistant Director for Human Resources Operations since 2012; Lisa Harlan-Williams, Ph.D., is the Assistant Director for Administration and Education and has been in this role since 2009; Ms. Mary Damewood, Assistant Director for Finance, manages the KUCC finance office; and Claire Koenig, JD, has served as KUCC's Chief Legal Officer in a full-time permanent capacity since March 2021 and in a part-time interim capacity since September 2019.

This capable and qualified group averages more than 10 years of Center administration experience. In 2020 the administration supported 171 members, $57 million in overall cancer related funding, and recruited 41 new members since 2016. In addition, a staff of more than 150 clinical trials employees have dotted line reporting to Christenson.

In response to prior critiques the Administration has established a more robust communications platform and in close collaboration with Dr. Krebill for Community outreach efforts through the Masonic Cancer Alliance. Highlights from this effort include a weekly Facebook Live series called Bench to Bedside that has reached over 572,000 people and the expansion of the Cancer Research Day to a full week including several new topics to encourage attendance of additional target audiences. Also, in response to the prior critique the Administration has developed far more comprehensive Research Program support, coordination, and management with the addition of a dedicated project manager and a more explicit planning process which is used to provide clarity on the role and responsibilities for program leaders throughout the grant cycle including better coordination for meetings and scientific project development. This effort compliments the coordination for the "Roadmap to Comprehensiveness" for which Ms. Christenson and her team provide support. These activities show strong demonstrated value of the Administration to the Center and help propel KUCC's mission.

The administration is well integrated with institutional offices representing the Center across several operational areas including technology commercialization, animal care, human subjects committee and human resources particularly with faculty recruitment. The administration, in collaboration with Mayo supports seven shared resources and one developing resource in the application. Administration has established policies on Faculty recruitment and membership that engage leaders across the Center to

identify areas of opportunity and growth in coordination with the strategic plan. Future consideration should be given on how to integrate the new Plan for Equity and Diversity into this process.

Space management is overseen by Harp in consultation with Jensen and Christenson. The space policy as described is well-thought out to foster scientific collaborations, mentoring, and general faculty interactions. The proposed addition of a new Cancer Center building is noteworthy and appropriate given the trajectory of the Center. However, the addition of this new space to an already robust physical footprint may require additional FTE to manage logistics for transition, occupation, and sustained oversight of space. Harp's commitment is to oversee pilot projects, CCSG supplements, grant development and facilities management. Further consideration should be given to ensure there is an appropriate percent effort to each of these critical tasks.

Grants Development and administration provided support for members via RFA circulation, coordinating the pilot project submission and review processes, CCSG supplements, and other pre-award associated tasks. The GDO assisted in an impressive 567 submissions totaling $59M during the prior period. Of note is the success in tripling fellowship/training awards over the last nine years and the number of CCSG supplements (four).

While it is evident through the quality of programs and faculty that the administration supports the Center's mission there are opportunities to continue administration's demonstrated progress from the prior submission. Inconsistencies in CCSG reporting metrics across several components were noted as concerns. A cancer relevant policy was provided at the site visit, but it was unclear from the application how this was applied. Additional consideration should be given to how to best facilitate and promote metrics curation and reporting throughout the Center particularly CRTEC.

Personnel: The KUCC administrative office is led by the Associate Vice Chancellor and Associate Director for Administration, Ms. Teresa J. Christenson, who reports directly to the Cancer Center Vice Chancellor and Director, Roy Jensen, MD. Ms. Christenson has organized the administrative office to efficiently facilitate and implement the Director's vision and support a cancer-focused culture that fosters collaboration and productivity among Cancer Center members. Ms. Christenson supervises approximately 50 employees through six direct reports and has dotted-line supervision for an additional 150-180 employees. She controls the agenda for all Leadership meetings and manages the strategic plan and priorities. In response to the previous review, KUCC's strategic goal was expanded to encompass the five aims of the Cancer Center.

Susan Harp, MFA, serves as the Director for Grant Development & Research Resources has successfully provided pre-award support for 162 faculty who submitted over 1,000 grant applications, resulting in $108 million in funded research, and coordinates the pilot project program, which has been in place for 16 years resulting in over 250 awards. She manages the Jewell Family Summer Cancer Research Program was founded in 2007 under her direction with 72 undergraduate, graduate, and MD/Ph.D. students who have completed the program. The GDO works with the university grants and contracts offices at KUMC, KU-L, Stowers, and CM on pre-award submissions. Since 2016 the GDO has assisted in submitting 567 grants resulting in $59 million awarded. The majority (95%) of this funding is peer-reviewed funding, with 60% awarded from the NCI. Fellowship/Training grants submissions more than tripled over the last nine years (nine awarded in 2011; 31 in 2020 comprising $3.7 million).

Ms. Theresa Leinwetter has served as the Assistant Director for Human Resources Operations since 2012. She works closely with many university departments and sits on several committees in compliance, diversity, equity and inclusion, performance improvement, the human resources process, and planning implementation. She has over 30 years of generalist human resources experience and manages recruiting, employee relations, program management, IT systems support, and employee events.

Lisa Harlan-Williams, Ph.D., is the Assistant Director for Administration and Education and has been in this role since 2009. She works closely with Jensen and Christenson and plans/organizes the process and timelines for annual CCSG progress reports, renewal submissions every five years, and yearly External Advisory Board (EAB) meetings.

Ms. Mary Damewood, Assistant Director for Finance, manages the KUCC finance office, which tracks payroll activities, manages KUCC cash flow, including tracking spending and incoming sources, and provides periodic financial management reports, including projections and analysis for KUCC's overall financial position. Ms. Damewood has served as the Assistant Director for Finance for three years. Her prior experience includes 20 years in health system finance with the last five years as Controller for the Olathe Medical Center system.

Claire Koenig, JD, has served as KUCC's Chief Legal Officer in a full-time permanent capacity since March 2021 and in a part-time interim capacity since September 2019. Koenig is KUCC's primary point of contact for all legal issues related to its research and education missions. Her in-depth knowledge of research agreements and processes makes her a valuable resource in conversations between KUCC and KU's research administration offices.

Assessment: Excellent to Outstanding merit

Budget: The budget is appropriate as requested.

ESSENTIAL CHARACTERISTICS

Physical Space is rated in the outstanding to exceptional range. The KUCC continues to add to its prior growth in physical space. Comprising more than 738,000 sq ft of research and clinical space KUCC is well positioned to accommodate the needs of faculty across the scope and breath of its research areas. The majority of the KUCC membership (72%) is located at the KUMC campus. This campus includes 170,000 sq ft of wet lab space in the Kansas Masonic Cancer Research Institute which houses administrative resources, shared resources (10,560 sq ft), as well as the Dept of Cancer Biology. Dr. Jensen was a key driver of securing renovation funding to better meet the needs of a growing Center in 2012. The KU Clinical Research Center offers an additional 82,000 sq ft of clinical space for the KUCC members. The donation of the building and funding for its renovation and maintenance was directed by Dr. Jensen. This space also allows close proximity for KUCC members to the CTSA services, housed on one floor, as well as many of its resources and facilities such as the metabolic kitchen, human physiology lab for exercise testing, and dual-energy x-ray absorptiometry scanning.

The Lawrence campus is located within a 45 mins drive and provides additional resources for current members (21) and potential new members. Importantly since the last renewal this campus completed a

new project called Central District. This space acts as the STEM hub of education and research and houses the Lawrence Science Building. This 280,000 sq ft space provides opportunities for future KUCC recruitment and collaborations that are interdisciplinary in nature. Also located at Lawrence is the 110,000 sq ft School of Pharmacy and the Shankel Structural Biology Center, additionally several SRs are located here including High Throughput Screening facility and Biotechnology Innovation and Optimization Center. Dr. Jensen was a key advocate for building appropriations on this campus and works closely with senior leadership to facilitate its use and development.

Stowers Institute for Medical Research hosts 11 additional KUCC members and provides access to several shared resources including bioinformatics, proteomics, and imaging. In addition, it has many research-support services such as conference rooms, an auditorium and library.

Children's Mercy Kansas City includes the 425,000 sq ft Children's Mercy Research Institute which began construction in 2017 and houses 16 KUCC members. The completed structure provides state of the art facilities for pediatric care; 750 medical staff, 20 board certified physicians, a mix of wet and dry lab space for genome analysis. This facility, along with Jensen working in close collaboration with Curran, provides robust support of pediatric oncology for the KUCC's catchment and beyond.

Clinical facilities are located on or near the KUMC campus and are jointly administered by the KUCC and KU Health System leadership. These facilities in aggregate include more than 5600 sq ft of space dedicated to Breast Cancer prevention and survivorship, a 7500 sq ft bone marrow transplant facility, in 62,500 sq ft of total outpatient space. KUCC's clinical trials office is located in 1340 sq ft of space near these facilities. Significant additions include a new patient tower which is 65% oncology and a proton center which will provide 29,000sq ft of space. These are located in Cambridge A, a 12-story 558,000 sq ft facility that houses 12 operating rooms, 132 patient beds for surgical oncology, medical oncology, bone marrow transplant, neurology and other oncology line services. This facility increases the inpatient Hematologic Malignancy and Cellular Therapeutics program by 100 beds. Finally, the Pediatric Clinical Research unit is located in Children's Mercy Hall and is a key space for the Pediatric Clinical Pharmacology core of the Pediatric Trials Network.

Administrative space is housed in 6,000sq ft on KUMC campus is an appropriate size and location to facilitate all the needs of a growing Cancer Center. Shared Resources occupy a total of 45,000sq ft dispersed across KUMC and KU-L campuses.

In the prior review, there was concern about the geographic spread of members and facilities. It should be noted that while dispersed KUCC Shared Resources have seen generally positive trends in usage across campuses over the last cycle (as demonstrated in the Shared Resource Management component) suggesting that members, independent of their location, have adequate access to all facilities and that KUCC leadership have been diligent in support of equal access policies. Likewise, the Center has developed an IIT team to facilitate KUCC investigators from study concept to execution. KUCC currently supports 55 KUCC-sponsored IIT and 12 multi-site IITs (as noted in CPDM). These positive metrics suggest that while still physically dispersed the Center is making strong efforts to promote a culture of collaboration. There was much emphasis placed on the new building that will consolidate cancer center researchers into a large new building with core facilities, vivarium, imaging facilities, etc. This would appear to be on a less than 5-year completion timeline, but at present there are efforts that are still very early, e.g., discussion of funding sources. Therefore, there is considerable hope and confidence that this will occur, but it remains largely aspirational. Strong progress has been made by KUCC leadership in gaining support for this important and transformational project.

Organizational Capabilities is rated as outstanding. The KUCC is a matrixed cancer center comprised of the University of Kansas (UK) which includes the Medical Center campus (KUMC,122 members) and the Lawrence campus (KU-L, 21 members) with two consortium partners, the Stowers Institute for Medical Research (11 members) and the Children's Mercy Hospital/Children's Mercy Research Institute (17 members). Since last cycle the status of Dr. Jensen has been elevated to that of a Vice Chancellor. Within this organizational structure, Dr. Jensen reports jointly to the Executive Vice Chancellor at the KUMC campus and the Provost of the KU-L campus, with dotted line reporting to the Stowers Executive Director/Chief Scientific Officer and the Children's Mercy President/CEO.

Three research programs, seven shared resources, and one developing resource are proposed by the KUCC. Membership criteria have been well defined and have now been expanded to be more inclusive of clinical researchers. Both full and associate members participate actively in cancer research and participate in KUCC activities. Full membership requires effort listed on a peer-reviewed grant, or to be an investigator on an IIT plus an author on a peer-reviewed publication or to have a significant role in the cancer center, i.e., leadership or administrative. Applications for full or associate membership are reviewed annually, with the Center Director having final decision-making authority regarding membership and program assignment.

Center Leadership includes one Deputy Director, eight Associate Directors, ten Program Leaders and Shared Resource Directors. Since last cycle, another AD position, for Education, has been added. While the number of number of ADs has been a prior concern, those being proposed match the shifting requirements of cancer centers. Of ten senior leaders, five are new, including ADs for Basic Science, Dr. Shrikant Anant, Cancer Prevention and Control, Dr. Christie Befort, Clinical Research, Dr. Weijing Sun, Health Equity, Dr. Ronald Chen, and Education, Dr. Danny Welch. Of ten Program Leaders, four are new, including: Drs. Sufi Thomas and Tomoo Iwakuma, in CB, Dr. Nikki Nollen, in CPC, and Dr. Priyanka Sharma in D3ET. Overall, this is considered a strong leadership team. Of seven shared resources, two are new: flow and nutrition. With microscopy being a developing resource. While these changes can be ascribed as a positive dynamic, they appear to underlie a high flux in as yet an evolving organization.

The Director, Deputy Director, and Associate Directors meet twice per month as the Associate Director's Council with a charge to advance the center's strategic goals, foster integration, and provide guidance on investments. Members of the Associate Director's Council join monthly with Program Leaders, as the Leadership Council. Additional advice to the KUCC Director comes externally from a Community Advisory Board, the Masonic Care Alliance Partners Advisory Board, and internally from Shared Resource Directors.

At the last CCSG review, an Institutional Advisory Board was just put in place. It is made up of those that the Cancer Center Director, Dr. Roy Jensen, reports to, including Executive Vice Chancellor (Dr. Simari), Provost (Dr. Bichelmeyer), Chief Executive Officer KU Health System (Dr. Page), Stowers Executive Director (Dr. Alvarado), Children's Mercy President (Dr. Kempinski). The makeup of this board is designed to provide advice on linking across consortium institutions. While the KUCC Director meets one-on-one with each of these individuals at least quarterly, the IAB only comes together to join the annual EAB. Thus, it is not clear that an open forum exists to integrate across the three institutions in the consortium. The KUCC Physician-in-Chief (Dr. Tsue) co-reports to the Cancer Center Director and the CEO KU Health System, with the role of integrating across clinical services. A Recruiting Committee focuses includes all Associate Directors, focuses on strategic recruitment, and 41 new external recruitments were completed since 2016.

An External Advisory Board is in place, its fifteen members have leadership positions across cancer-relevant institutions. It has provided a strong positive influence that continues to play an import role in the success of the center. An important measure of such relates to a major programmatic restructuring. Since the last cycle, the two population science programs have been combined into a single Cancer Prevention and Control Program. This is considered a very important and substantial improvement.

KUCC's catchment area includes the entire state of Kansas and 18 counties in Western Missouri. Of the 4.5 million people across these 123 counties, they include a significant underserved population, and 1 million reside in rural or frontier settings. The establishment of a Catchment Area Committee, coupled to their development and use of unique software, such as OPTIK, creative programs such as PIVOT, and their investment in creating an alliance of community oncology partners (formally the Midwest Cancer Alliance, now through new donor-based funding, called the Masonic Care Alliance) provide an impressive set of integrated strategies to understand and address unmet needs of the population.

The new formation of a dedicated Educational Program headed by a new AD position, held by Danny Welch, represents a strategically important organizational achievement that is poised to significantly bolster CRTEC. Along with Assistant Director, Dr. Lisa Harlan-Williams, this program has experienced, excellent and complementary leadership. Each has led national and local educational advances, respectively, with each generating education-focused scholarly publications that will broadly inform and advance the field. The current approach of dividing graduate and higher, and undergraduate and lower training efforts between them seems to be working in the context of this newly formed program. Based on programmatic growth, it will be important for future goals to focus on integration across the learning spectrum. Of training grants listed in association with the program, the cancer focus of several is not clear.

The Office of Cancer Career Development (OCCD) was developed to coordinate activities across different KUCC partnering institutions, constitutes a key operation, and time will tell how well it functions. Given the multiple sites and consortium institutions, an important goal will be to codify and enhance the activities of the OCCD. To date, three new graduate programs have been developed: Cancer Biology, Biostatistics and a Stowers based program. Their integration across sites should evolve with time. The KUCC onco-psychology program, accredited in 2019, is poised to move the field in important and creative ways. Overall, these are considered to be important accomplishments, several newly initiated, and some quite creative. Several partnering initiatives were described, a few were creative, some with depth, some not. Continued maturation of the Education Program should remain a focus of senior leadership. Its success in doing should yield metrics related to cancer-specific training grants, such as T-series or similar.

The KUCC is spread across a number of locations, broadly listed as four: University of Kansas (Kansas City and Lawrence locations) and two consortium institutions (Stowers Institute for Medical Research, Children's Mercy Hospital). However, the actual medical center has locations in Kansas City, Wichita, and Salina. Further, within the Kansas City location, buildings in the West District are geographically separate, and the Clinical Research Center is three miles south. That all of these entities come together to form KUCC highlights a high-level organizational capability and is impressive. While strategies to further unite and bring these entities are identified as a goal, there are no clear details provided as to how this will be achieved. The MOU with Stowers was put in place in 2009 and was most recently renewed for another five years in 2021. The MOU with Children's was put in place in 2015, renewed 2020. These relationships continue to mature in important ways, with agreements in place to address disputes and to align fundraising initiatives. Several instances of impressive cooperation and engagement are evident, especially in fund raising.

The KUCC leadership team engaged in an ongoing refinement of the KUCC strategic plan. This plan includes key pillars of drug therapeutics, optimal environment, education, community, and collaboration. In 2017, the senior leadership team prioritized a subset of strategic plan objectives within a “Road to Comprehensiveness Initiative”. This initiative had a sharp focus on addressing issues in the prior CCSG review with emphasis on addressing geographic dispersion, elevating community outreach and engagement, recruitment of key faculty, submission of INDs, enhancing enrollment in clinical trials, addressing consortium criteria, training and education and multi-investigator programmatic grants. At the site visit, Dr. Jensen described the strategic planning process which included broad engagement of KUCC members, leadership, and the community. Future plans highlight the construction of a central cancer building. This will serve an important integrative function but will not solve fixed distant location integration aspects. While monies to support this building have not yet been committed, senior leadership across the KU system conveyed that this was a priority funding initiative and outlined a path forward.

Overall, the organizational capabilities of the center have facilitated and added value to the cancer mission as well as fostered scientific interactions and joint initiatives among external partners. Significant progress is being made in aligning vision and goals. Impressive organizational inroads in aligning care across the catchment area are evident. Strategic planning activities are evident, and various committees have been assembled to implement and evaluate the strategic plan. An extensive set of initiatives and goals are presented in the application, along with an impressive set of successful funding initiatives. There have been notable advances and achievements. However, aspects that are necessary and geared to the specific geographic make up of KUCC and its integrated coordination across sites have yet to be addressed. Achieving a more stable balance between dynamic adaptability and high leadership flux will serve to enable the design and implementation of such long term strategies.

Transdisciplinary Collaboration and Coordination is rated as outstanding. The KUCC has goals of facilitating transdisciplinary research which permeate all of its activities. The KUCC pilot project grand program mandates team science and collaborative interactions. In the past funding period, the KUCC pilot program supported 51 pilot project grants to 48 different cancer center members, which had a 10.8-fold return on investment for new grant funding. Awardees published 100 articles and initiated three IITs. KUCC members published 2,411 papers in the past funding period with 12% in high impact journals (≥10 impact factor), 32-55% intra-programmatic, 20-27% inter-programmatic and 58-75% inter-institutional collaboration percentages among the programs. In particular, the integration with partner institutions appears to work well, as a majority of the research papers involve more than one of the consortium partners. The number of multi-PI grants has increased over the last funding period from 42 to 60 (including a COBRE grant). Multi-disciplinary efforts are supported in the academic faculty promotion criteria. The application cites major achievements in advocacy for specific public policy changes as an example of transdisciplinary collaboratives driven by the Prevention and Control Program working with basic and clinical scientists and advocate groups.

The KUCC Leadership has promoted transdisciplinary research primarily through its drug discovery/development efforts. All three programs are brought together under the translational research umbrella under the leadership of Dr. Scott Weir, who has overseen the development of the drug discovery program. The Drug Discovery and Development Steering Committee (D3SC) includes representatives from all three Cancer Center programs necessary disciplines, including basic, translational, and clinical scientists, and the KUCC consortium partners. There is an analogous

committee for experimental therapeutic trials, the Investigator-Initiated Trial Steering Committee. Collaborations are further encouraged by the requirement in the Pilot Project Program for collaborative interactions. The Investigator Initiated Trial (IIT) Steering Committee (IITSC) was developed to foster and overcome obstacles for developing new IITs, which has shown impressive increases in the numbers of IITs and patient accruals to IITs.

One example of the development of IIT of low-dose daunorubicin-based treatment for pediatric leukemia based on hematopoietic stem cell studies conducted by KUCC members at Stowers, CM and KUMC and with the use of the shared resource high throughput screen. The KU School of Pharmacy has an exceptional record of spinning-off pharmaceutical companies. KUCC has advanced five investigational drugs into clinical trials in the last review period by partnering with pharmaceutical companies (partly through a public-private partnership in Kansas City) and NIH.

A minor weakness is the production of paradigm-shifting research, new synthetic drugs, and impact on patient care could be higher based on the resources, expertise, organizational efforts available in the consortium and commercial/business infrastructure available in the community.

Cancer Focus is rated as outstanding. During the current review period, KUCC underwent a programmatic organization that reduced the number of research programs from four to three. The resulting Cancer Biology, Cancer Prevention and Control, and Drug Discovery, Delivery and Experimental Therapeutics programs demonstrate strong cancer focus based on member publications, and extramural grant support.

Over the past 5-year funding period, the center has experienced a decrease in membership from 183 in the last application to 171 in the current application. The decrease is explained in the application as being the result of more stringent membership criteria. The NCI funding base of $10.1 million represents a strong increase from $7.8 million previously. Despite a reduction in membership, overall cancer related funding (directs) increased from $46.3 million in to $51. million 21 (excluding training). KUCC also competed successfully for an impressive number of CCSG P30 supplements since 2016. It is notable that the number of MPI team-based grants and publications that are inter-programmatic has grown over the past funding period.

Cancer focus is also evidenced by increases in enrollment to therapeutic trials. Accruals to interventional treatment trials grew from 2462 in the last application to 3965 in the current application. A total of 594 patients (11.6% of patients) accrued to interventional treatment clinical trials in 2020 at the 4 participating KUCC sites. The number of investigator-initiated oncology trials has also increased steadily and five KUCC discoveries of anti-cancer agents were advanced to clinical trials in the current grant period.

The number of cancer-focused manuscripts has increased over the 5-year funding period, during which cancer center members published 2,411 publications (~482/year) where KUCC members published 1,741 publications (435/year.) during the prior funding period. The impact of KUCC cancer related research from 2016-2020 is reflected in 12% of publications appearing in journals with impact factors $\geq$10.

Over the 5-year funding period, there has been recruitment of 41 faculty members, all of whom are cancer-focused. These recruits include several high-profile investigators, including Ronald Chen, Chair of Radiation Oncology and Associate Director of Health Equity.

The center appropriately addressed prior reviewer comments suggesting a shift to increase cancer-focused research in the catchment area, especially as it relates to the African American and Native American populations. The Cancer Biology program is to be commended on efforts to work with the Drug Discovery, Delivery, and Experimental Therapeutics research program to translate their scientific discoveries to investigator-initiated clinical trials. Inter-programmatic efforts across the 3 KUCC programs are increased in the current funding period. Despite these strengths, a more objective rigorous process may be needed for categorizing the level of cancer relatedness for research grants.

Institutional Commitment is rated as exceptional. Support for the KUCC continues to be exceptional both from center director authority standpoint as well as with regards to financial support. However, as a minor point, the write-up itself is a bit confusing since some total amounts are calculated based upon the year that Dr. Jensen arrived (i.e., 2004) with other calculations referencing 2007 or the current grant period. Even with these grantsmanship shortcomings, perusal of the table for institutional commitment broken down by budgetary periods is quite impressive regarding the level of support provided by the institution, state, and community.

The KUCC receives significant financial commitments from its parent institutions (The University of Kansas and its Medical Center), its clinical partner (The University of Kansas Health System), its consortium partners (Stowers and CM), the Masonic Cancer Alliance, the Johnson County Education and Research Triangle (JCERT) tax, the State of Kansas, and the philanthropic community. Excluding the $150M for the building of the cancer-related functions of Children's Mercy Research Institute, there was over $300M provided to the Cancer Center from the state, university, the health system, philanthropy, the Johnson County Research Triangle, the Masonic Cancer Alliance, Children's Mercy Hospital, and the Stower's Institute. Of note, the KUCC obtains considerable support from a one-eighth cent sales tax that goes exclusively to the Cancer Center and has been in place since 2008. In addition, the state of Kansas has provided $5M annually, and beginning in 2021, this will increase to $10M annually. It is also notable that the KUCC has its own Human Resources Department, Communications Team, Network and Systems Support Group, Legal Counsel, and Event Planner. It is uncommon for matrix cancer centers to have all of these components which is more consistent with a stand-alone cancer center.

The KUCC has a level of autonomy and authority superior to other departments, centers, or institutes with regard to space, positions, and discretionary resources to ensure organizational stability and fulfillment of the KUCC vision. Departments provide academic appointments for all faculty recruitments. There is a Grants Development Office and a clinical trials office to support members competitive grant applications and clinical trials respectively. The authority of the director is well delineated and well structured. It is clear that Dr. Jensen is intimately involved at the highest level of institutional decision making. He has adequate authority to allocate KUCC research space and resources; develop the KUCC budget including all cancer-related philanthropic funds and fundraising activities; recruit faculty to further KUCC's vision in cooperation with department chairs, establish and oversee the management of KUCC research programs, shared resources and cancer-related clinical activities. Succession planning is discussed, and if Dr. Jensen is not able to serve in his capacity as Director, Dr. Godwin (Deputy Director) will be appointed as Interim Director and a national search will be initiated to fill this

position. Overall, the institutional support is robust, and discretionary resources under the direct control of the cancer center appear significant.

Center Director is rated as exceptional. Dr. Jensen has been Director at KUCC since 2004 (recruited from Vanderbilt), and in 2021 the Vice Chancellor of KUCC. A renowned breast cancer pathologist and scientist, Dr. Jensen's research has increased our understanding of the molecular and cellular mechanisms underlying breast cancer pathogenesis. His faculty appointments include Professor of Pathology and Laboratory Medicine, Professor of Anatomy and Cell Biology, Professor of Cancer Biology, Professor of Biomedical Engineering, and Adjunct Professor of Molecular Biosciences at the University of Kansas. Since 2005, he has served as the William R. Jewell Kansas Masonic Distinguished Professor of Cancer Research. Dr. Jensen has been a regional and national leader in Cancer on many levels. Dr. Jensen has served on NCI subcommittee A both as member and chair, and is immediate past President of the AACI. He has served on over 70 CCSG site visits with 27 as visit Chair, serves on many NCI Cancer Centers EABs, and has made many myriad contributions to the mission against cancer both in cancer, in his own area of research, and as a cancer organizational leader.

Director Jensen reports to the Executive Vice Chancellor at KU Medical Center and the Provost at the KU-Lawrence campus. Additionally, Dr. Jensen reports to Stowers President and CEO, the Children's Mercy President and CEO and KU Health System CEO. Deputy Director Godwin would be appointed as Interim if Dr. Jensen unable to fulfill the role. Dr. Jensen is stipulated to have authority over cancer research space and resources, KUCC budget and philanthropic activities, oversees cancer related clinical activities across KU Health System in conjunction with KUCC Physician in Chief. Dr. Jensen has helped expand the KUCC endowment significantly during his tenure and raised over $467 million in philanthropy for cancer since his appointment.

Dr. Jensen is highly experienced, well situated, and superbly well qualified to lead the KUCC Cancer Center and has the appropriate authority and institutional mandate to continue to be successful in this role. In the current funding period, Dr. Jensen led the refinement of the KUCC strategic plan and the recruitment of 41 new investigators into the cancer program. Under his leadership, KUCC has increased its cancer related funding base and achieved robust inter- and intra-programmatic publication metrics. His significant contributions to the national efforts in cancer has expanded the collaborations and reach of KUCC, and deeply increased the regional impact through KUCC research and the philanthropic support of that research. He is eminently qualified to serve as KUCC's director.

BUDGET RECOMMENDATION

The site visit team did not make any reductions from the total direct costs of the CCSG. In total direct costs, the current budget is $1,540,000 (from Data Table 5); requested budget is $1,705,000 (from Data Table 5 and/or Face Page); and the recommended budget is $1,705,000. The site visit team recommends that the budget be evaluated by the NCI IRG Cancer Centers Study Section (A), as needed.

The NCI IRG Cancer Centers Study Section (A) concurs with the site visit team's recommendation and recommends $1,705,000 direct costs. This recommendation does not reflect an evaluation of the institution's indirect cost rate.

The budget tables that follow are provided as informational item only. The official recommendation for support is provided under the heading, RECOMMENDED BUDGET/ NCI IRG CANCER CENTERS STUDY SECTION (A), after the NCI IRG CANCER CENTERS STUDY SECTION (A) meeting has met.

COMMITTEE BUDGET RECOMMENDATIONS/SITE VISIT TEAM'S RECOMMENDATIONS

The table below summarizes the estimated effects on the original amounts requested by the applicant of implementing the budgetary changes recommended by the reviewers and summarized in the Budget section(s) of the Summary Statement above. The table below does not take into account either additional information that may be provided by the applicants in response to administrative requests for updates or additional administrative changes that may be required to meet Institute funding policies, either or both of which may result in a significantly different final recommended budget figure. Consequently, applicants should make no inferences from these figures about what the final budget might be should an award be possible.

	First Year Requested Direct Costs $	First Year Recommended Direct Costs $
Program Leadership (including other budget categories, where appropriate)	90,555	90,555
Cancer Research Training and Education Coordination	29,510	29,510
Leadership, Planning and Evaluation	255,102	255,102
Developmental Funds (including staff investigators, where appropriate)	336,614	336,614
Administration	104,811	104,811
Biospecimen Shared Resource	115,903	115,903
Biostatistics & Informatics Shared Resource	194,062	194,062
Clinical Pharmacology Shared Resource	56,513	56,513
Flow Cytometry Shared Resource	15,014	15,014
Lead Development & Optimization Shared Resource	76,556	76,556
Nutrition Shared Resource	20,890	20,890
Transgenic & Gene-Targeting Shared Resource	78,215	78,215
Community Outreach and Engagement	142,241	142,241
Clinical Protocol & Data Management (CPDM) Data & Safety Monitoring	114,360	114,360
Protocol Review and Monitoring System	39,723	39,723

SUMMARY OF RECOMMENDED BUDGETS/SITE VISIT TEAM'S RECOMMENDATIONS

Budget Categories	YEAR 11 $	YEAR 12 $	YEAR 13 $	YEAR 14 $	YEAR 15 $
Salary, Wages and Fringe Benefits	1,327,586	1,327,586	1,327,586	1,327,586	1,327,586
Equipment	0	0	0	0	0
Travel	4,000	4,000	4,000	4,000	4,000
Participant/Trainee Support Costs	0	0	0	0	0
Other Direct Costs (excluding Consortium)	345,594	345,594	345,594	345,594	345,594
Consortium Costs	43,399	43,399	43,399	43,399	43,399
Direct Costs	1,720,579	1,720,579	1,720,579	1,720,579	1,720,579
Indirect Costs	936,200	936,200	936,200	936,200	936,200
Total Costs	2,656,779	2,656,779	2,656,779	2,656,779	2,656,779

RECOMMENDED BUDGET/THE NCI IRG CANCER CENTERS STUDY SECTION (A) *

Budget Categories	YEAR 11 $	YEAR 12 $	YEAR 13 $	YEAR 14 $	YEAR 15 $
Total Direct Costs	1,720,579	1,720,579	1,720,579	1,720,579	1,720,579
Total Costs	2,656,779	2,656,779	2,656,779	2,656,779	2,656,779

* The official recommendation for support is indicated under the heading, RECOMMENDED BUDGET/NCI IRG CANCER CENTERS STUDY SECTION (A). (This information may differ from the amounts in the tables, COMMITTEE BUDGET RECOMMENDATIONS/SITE VISIT TEAM'S RECOMMENDATIONS and SUMMARY OF RECOMMENDED BUDGETS/SITE VISIT TEAM'S RECOMMENDATIONS.) Appropriate escalation factors may be added in the event of an award.

Footnotes for 2 P30 CA168524-11; PI Name: JENSEN, ROY A.

NIH has modified its policy regarding the receipt of resubmissions (amended applications).See Guide Notice NOT-OD-18-197 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Cancer Centers Study Section (A)
National Cancer Institute Initial Review Group
NATIONAL CANCER INSTITUTE
Dr. Roy A. Jensen (2 P30CA168524-11)
NCI-A RTRB-I Work Group# 1
02/14/2022 - 02/16/2022

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Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.

MEETING ROSTER

Cancer Centers Study Section (A)
National Cancer Institute Initial Review Group
NATIONAL CANCER INSTITUTE
NCI-A
05/12/2022

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