March 7th, 2014

Re: NOVEL EDUCATIONAL INTERVENTIONS FOR COMMUNITY ONCOLOGISTS AND PATIENTS:
OPTIMIZING RENAL CELL CARCINOMA OUTCOMES THROUGH ENGAGEMENT

Dear Review Committee:

The Duke University School of Medicine and Duke Clinical Research Institute are pleased to request an educational grant in the amount of $484,000 to address Health Care Provider, Patient, and System of Care Gaps in the treatment of renal cell carcinoma (RCC). This initiative intends to address specific unmet needs and clinical gaps in the area of RCC assessment and management by improving the competence and performance of clinicians as well as by addressing educational gaps among patients and caregivers. The proposed technology solution addresses the acute need to evaluate and realign systems of care to optimally treat RCC patients.

The Duke University School of Medicine will carefully follow the Essential Area, Policies, and Standards for Commercial Support of the Accreditation Council for CME (ACCME) during the planning, development, and implementation of this initiative. In accordance with such guidelines, commercial supporters may have no influence on the educational design, activity content, faculty selection, or audience. Please find attached a detailed needs assessment, educational design and execution plan, outcomes assessment strategy, and budget summary for this activity.

Thank you for your consideration of this novel educational initiative. Please feel free to contact us if we can assist your review in any way.

Sincerely,

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NOVEL EDUCATIONAL INTERVENTIONS FOR COMMUNITY ONCOLOGISTS AND PATIENTS: OPTIMIZING RENAL CELL CARCINOMA OUTCOMES THROUGH ENGAGEMENT

Submitted by

Center for Learning Health Care, Duke Clinical Research Institute

Center for Educational Excellence, Duke Clinical Research Institute

Duke Cancer Institute
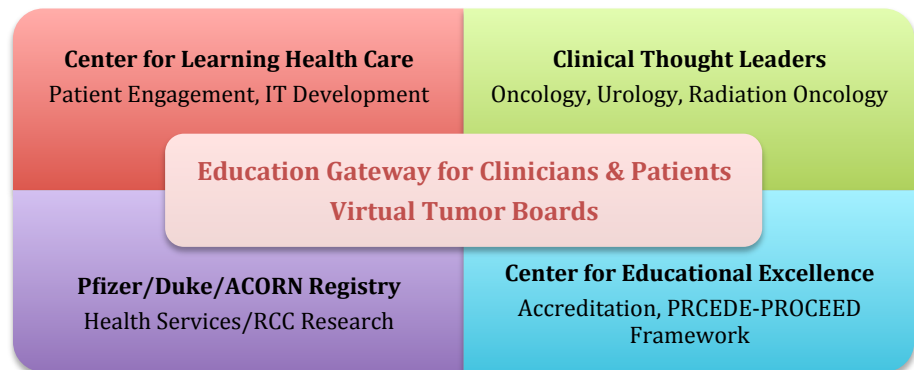
Duke Cancer Network

ACORN Network

1.   Overall Goals & Objectives - Duke University respectfully submits this proposal to support an Independent Grant for Learning and Change (IGL&C) designed to achieve improved renal cell carcinoma (RCC) management and outcomes in the community by addressing barriers that challenge patients and clinicians. The low prevalence and rapidly changing therapeutic landscape for RCC make it difficult for community oncologists to gain the requisite experience to treat the disease and it can be daunting for clinicians to fully study the nuanced clinical trial and real world data underlying current guidelines. Despite being central to the care paradigm, patients and their caregivers are minimally engaged. A creative solution is needed.

In order to overcome the systems-level gaps identified, our proposed initiative will leverage a sophisticated, engaging learning platform to **(1)** guide providers through treatment decisions and the management of adverse events (AEs), which are unique to RCC and complicate the delivery of high quality care; **(2)** leverage a patient-facing portal to provide solutions to improve patient education and insights; and **(3)** facilitate virtual tumor boards wherein challenging patient cases are presented in order to provide nuanced guidance to clinicians. **A number of attributes position the Duke team to conduct this work:**

- The investigators have conducted an extensive retrospective review of real world RCC treatment patterns since 2007, in conjunction with the Duke Cancer Network (DCN), ACORN Research, and Pfizer. As of early 2014, we have assessed over 600 patients with RCC, understanding the treatment sequences, outcomes, AEs and patient experiences.[1-3] This provides crucial insights with which to optimize our approach.
- The multi-disciplinary team includes thought leaders across the fields of clinical care with substantial traction in the community, including sitting on the National Comprehensive Cancer Network (NCCN) RCC Guidelines.
- The Center for Educational Excellence (CEE) at the Duke Clinical Research Institute (DCRI) is well versed in the development, delivery and assessment of educational interventions, maximizing the likelihood of success.
- The Center for Learning Health Care (CLHC), also in the DCRI, includes international thought leaders in the engagement and education of patients and caregivers including in the generation of patient reported outcomes.

The overall aim is to develop novel, proven methods to improve knowledge, competence, and performance in the care of the RCC patient while also demonstrating how to better involve patients in their own care. The program has a high likelihood of success due to the expertise of the groups outlined in Figure 1.

Figure 1. Core Strengths of Duke/ACORN Proposal

Center for Learning Health Care
Patient Engagement, IT Development

Clinical Thought Leaders
Oncology, Urology, Radiation Oncology

Education Gateway for Clinicians & Patients
Virtual Tumor Boards

Pfizer/Duke/ACORN Registry
Health Services/RCC Research

Center for Educational Excellence
Accreditation, PRCEDE-PROCEED Framework

1.1 Objectives for this proposal directly align with what is needed for the RCC community:

- Develop a unified system with which to provide novel educational tools to both clinicians and patients, designed using well established PRECEDE-PROCEED framework of health education program planning.
- Demonstrate the impact of this system on outcomes for both providers and patients through improved patient level outcomes using predefined endpoints such as total time on therapy and quality of life (QOL) as tested across community practice networks.
- Assess provider level outcomes for improvement in individual healthcare provider (HCP) knowledge, skills, attitudes and behaviors.

1.2 Project leadership for this endeavor consists of:

- Principal Investigator (PI) -Bradford Hirsch, MD, MBA: Dr. Hirsch is a practicing genitourinary medical oncologist who is the PI of the ongoing prospective and retrospective Pfizer/Duke RCC registries. As Director of Clinical Informatics and Learning Labs for the CLHC within the DCRI, he has extensive experience designing novel data acquisition and patient engagement strategies for registry, patient advocacy and federal programs.
- Design and Implementation - Charles Scales Jr, MD, MSHS: Dr. Scales is a practicing urologist, experienced with medical education and health services research. As a Robert Wood Johnson Foundation Clinical Scholar at UCLA, he trained in community engagement techniques as well as program planning and evaluation using mixed methods approaches.
- IT Innovations – Kevin Monroe, MBA: Kevin Monroe is Director of Strategy and Innovation for the DCRI and has taken leadership in building technology solutions throughout the institute over the past decade. His expertise lies in novel education solutions and registry development, positioning him well to lead the IT aspects of this endeavor.
- Clinical Thought Leadership: The Duke Cancer Institute team spans specialties involved in the care of RCC patients including: Daniel George, MD (Professor and Director, GU Oncology), Michael Harrison, MD (Assistant Professor, GU Medical Oncology), Bradford Hirsch, MD (Assistant Professor, GU Medical Oncology), Edward Rampersaud, MD (Assistant Professor, Urology/Surgery), John Kirkpatrick, MD, PhD (Assistant Professor, Radiation Oncology), and Trish Creel, RN (Lead Nurse, GU Oncology)
- Patient Thought Leadership: Each site will identify an RCC patient/caregiver who will form our patient leadership team. The 14 members will take part in structured interviews during the pre-intervention assessment and will then meet monthly via webex to discuss both their experience with the system and provide guidance.
- CME Leadership – Chitra Subramaniam, PhD, MS: Dr. Subramaniam is Assistant Director of the Center for Educational Excellence and Associate Dean for CME whose mission is to promote excellence in clinical care through global education of providers, patients, and sponsors. She has led similar efforts across a variety of sponsors.
- Dissemination: Haymarket Medical Education has a longstanding history of collaboration with accredited providers from academic institutions and specialty organizations to scale CME programs. They reach nearly 750,000 physicians, nurses, pharmacists, physician assistants, and nurse practitioners every month worldwide and will lead the outreach effort.

2. Technical Approach

2.1 Needs Assessment: Recent assessments have outlined key target areas that this proposal will address. A recent assessment of Practice Gaps and Educational Needs for RCC provided critical information to guide the approach. The mixed methods analysis revealed that education is needed to improve understanding among community oncologists of **(1)** the use of new agents, **(2)** predictors and treatments for poor prognosis patients, **(3)** dosing and switching based on patient response, **(4)** recognizing non-radiologic progression, **(5)** the role of multidisciplinary teams, and **(6)** integration of quality of life (QOL) data. While each of these needs is distinct, an educational approach that follows the longitudinal experience of the patient across their healthcare interactions can address them.

The ongoing retrospective registry that has been established between Pfizer, Duke and ACORN since 2007 further identified areas of need,[1-3] while also accentuating those detailed above. While publications on overall and progression free survival have already been published from this collaboration, further analyses of adverse events and patient QOL derived from patient reported outcomes (PROs) are nearing submission. The lessons learned from this project are robust. The additional high priority areas identified include the need for **(7)** education of patients and caregivers so that they may be active participants in the process, **(8)** optimization around the management of real world AEs, **(9)** deeper understanding of how to prolong time on therapy, and **(10)** integration of real world evidence and comparative effectiveness research into decision making.

We found that the low prevalence and rapidly changing therapeutic landscape for RCC makes it difficult for community oncologists to gain requisite experience and it can be daunting for clinicians to fully study the nuanced clinical trial and real world data underlying guidelines. There was significant variation among treating clinicians with up 8 lines of therapy administered and innumerable combinations, some of which would no longer be considered standard of care. The AEs and treatment approaches in RCC differ dramatically from other cancer types, further complicating the picture. For instance, clinicians may not know what patients experience as nausea is actually caused by gastritis and therefore poorly treated by anti-emetics. 98% of patients experienced an AE during treatment that met the threshold of documentation by a clinician. These real-world insights gained through careful analyses of our registry and day-to-day clinical experience have prepared us for this project.

2.2 Project Sites - The project will include 14 sites across ACORN and the Duke Cancer Network (DCN). The primary audience for this offering consists of clinicians (physicians and allied HCP) treating RCC at community (ACORN) and hybrid academic-community

Table 1. Practice Characteristics across 9 ACORN Sites in 2013					
Site Location	Medical Oncologists	RCC Patients			Mean # pts /oncologist
		New	Established	Total	
Royal Oak, MI	2	1	2	3	1.5
Atlanta, GA	8	10	15	25	3.1
Memphis, TN	12	11	43	54	4.5
Kalamazoo, MI	10	9	9	18	1.8
Newark, DE	6	2	9	11	1.8
Gastonia, NC	8	10	8	18	2.3
Lincoln, NE	5	2	13	15	3.0
Marietta, GA	19	17	42	59	3.1
Savannah, GA	6	10	19	29	4.8
Totals	**76**	**72**	**160**	**232**	**3.1**

(DCN) sites, along with RCC patients and their caregivers at the same sites. ACORN Research, LLC and the DCN are described at length in Appendix D. In brief, ACORN is a network of community practices in the Midwest and east coast (Table 1) including 9 clinical sites at which RCC patients were seen in 2013. Across these sites, 76 clinicians cared for 232 RCC patients.

The DCN includes 10 clinicians at 5 sites in rural North Carolina who treated 39 patients with RCC during 2012. This equates to a mean of 3.2 RCC patients per year for each of the clinicians at the DCN and ACORN, accentuating the limited experience a given clinician may have treating RCC. While we believe that the 14 sites across ACORN and the DCN represent the optimal balance between

Table 2. Practice Characteristics across 5 DCN sites in 2012					
Site Location	Medical Oncologists	RCC Patients			Mean # pts /oncologist
		New	Established	Total	
Smithfield, NC	2	8	4	12	6
Henderson, NC	2	4	3	7	3.5
Oxford, NC	1	0	3	3	3
Laurinburg, NC	2	8	4	12	6
Lumberton, NC	3	2	3	5	1.7
Totals	10	22	17	39	3.9

scale and focus for this endeavor, further strengthened by prior abstraction of clinical data, numerous further sites could be captured through relationships with DCN research sites and across the US Oncology Network, should difficulties be encountered or more scale be needed.

2.2 Project Implementation - The goal of this project is to develop a novel technology platform that has been tested across two community practice networks (ACORN and DCN) for its ability to provide tailored, just-in-time education to patients and clinicians in order to improve relevant outcomes and maintain engagement. While the required budget is $485,000, the mixture of thought leadership, methodological rigor, and educational expertise outlined in the implementation plan speak to the potential for a scalable solution that will have wide impact. The proposed program will be structured in three stages: Stage 1 - pre-assessment to understand current practices gaps and methods to address them, Stage 2 - interventions using the portal for clinicians and patients, and Stage 3 - post-assessment analysis of impact.

2.2.1 Stage One: Pre-Intervention Assessment - The overall objective of this phase is to inform the design of the patient- and physician-facing aspects of the educational delivery by using a learner-oriented, participatory approach to design the program. The approach is organized around the PRECEDE-PROCEED framework for planning health and education programs. This planning framework is well established[4] and comprises 4 stages that inform program design, and four stages that follow program implementation.[5,6] In the planning stage for the proposed educational program, we will concentrate our efforts on the *social assessment, epidemiologic assessment,* and *environmental assessment* phases of the PRECEDE-PROCEED framework. The social and environmental assessments will specifically identify learner needs, key QOL issues, and factors which will promote or inhibit utilization of the platform. The epidemiologic assessment will provide insight into the clinical and PRO of the current system of care in the existing network. These three phases will optimize uptake and sustainability of the learning platform for physicians and patients.

Framework: Using a mixed methods approach, including key informant interviews, surveys, and secondary analysis of clinical and PRO data already gathered from the participating DCN/ACORN network practices, we will develop a granular understanding of the needs and learning style of our specific target population. This work will be organized under the following specific aims:

- From among educational priorities noted above, we will determine which practice gaps and educational needs are most important for the physician stakeholders in the DCN/ACORN,
- Identify which learning modes (i.e., webinar, interactive, case-based, question/answer, virtual tumor board) will fit best into the workflow of busy community oncologists and how to integrate platform use into workflow; and,
- Identify high priority educational needs for, and desired learning styles of patients and caregivers with RCC, in order to maximize platform uptake in the population.

Approach: Three sources of data will be integrated to accomplish the proposed aims of the Pre-Intervention Assessment. The *social assessment* and *environmental assessment* phases will be accomplished with the use of quantitative data from surveys and qualitative data from semi-structured interviews, as follows:

- **Physician and Patient Surveys**: First, quantitative data will be gathered via surveys directed towards all HCPs treating RCC patients and the patients/caregivers themselves in the target practices. The Physician Survey will cover practice gaps and educational needs previously identified (i.e., use of new agents, dosing and switching based on response, integration of QOL data), to determine gaps and needs most important to network physicians. In addition, we will query physicians about what learning mechanisms (i.e., interactive cases, virtual tumor boards) most interest them and how they might use the mechanisms within their existing clinical workflow. The Patient Survey will help identify **(1)** what QOL issues are important to patients within the target practice networks, **(2)** educational topics viewed as high priority by patients, and **(3)** preferred learning styles of patients.
- **Key Informant Interviews:** From among survey respondents, we will select 25 physicians and 25 patients (random sampling from DCN and ACORN) to gather qualitative data regarding their views on educational needs and practice gaps (physicians), key QOL issues (patients), and learning styles (both physicians and patients). The semi-structured interviews will be informed by the quantitative survey results. For example, if survey results indicate that dosing and switching based on AE profiles is a key educational need within the DCN/ACORN practices, then the interview would focus on a recent experience with dosing and switching in order to explore the range of structural (i.e., care organization) and process factors associated with physician decision-making. To explore physician-learning styles, the interview could query the last time a physician experienced an information need and the process she used to address the need. Similarly, the 25 patient respondents will provide granular qualitative data regarding their experiences with treatment. The sample size (25 physicians, 25 patients) will provide an appropriate number of key informants with which to achieve concept saturation.

The *epidemiologic assessment* will be informed with secondary analysis of previously gathered data from network practices.

- **Secondary Analysis of Existing Data:** Through the established DCN/ACORN database, granular data are available on key metrics (e.g., dosing, treatment selection, time on therapy). Thus, using the practice gaps previously identified, we can use this baseline data to provide an objective assessment of potential opportunities to improve care within the DCN/ACORN networks. The baseline objective data will augment the subjective data gathered by survey and key informant interviews, and will provide the basis of the social, epidemiological, and environmental assessment within the PRECEDE-PROCEED framework. In addition, the Duke/ACORN database contains PROs for a subset of practices; secondary analysis of this data will supplement patient surveys and interviews with more objective patient-level outcome data.

2.2.2. Stage Two: Educational Intervention: As discussed previously, the proposal is novel in that it consists of three key offerings integrated into a unified system: **(1)** a sophisticated education platform for clinicians that is engaging and will walk clinicians through the management of patients across time and settings, including through treatment decisions and the management of AEs which are unique to RCC and complicate the delivery of high quality care; **(2)** a patient-facing portal with videos, readings, links and webinars with which to provide patients with the education and insights to empower themselves; and **(3)** a series of 10 virtual tumor boards where challenging patient cases can be presented and discussed. Altogether, this will form a supportive environment that will optimize care across stakeholders and settings. By providing coordinated, focused educational content to patients, caregivers, and clinicians that is accessible, easy digested, and targeted, it will drive alignment and optimize care. All participating sites will be required to participate in kick off/launch webinars to orient and inform participants about the program while sharing system challenges and barriers.

A. Clinician Education Gateway: We propose to adapt our clinician-facing learning system to (1) walk clinicians through the critical decision nodes identified in the NCCN guidelines and literature, (2) allow customization of content to a particular patient's presentation, and (3) enable providers to resume learning modules throughout the treatment course, ensuring timely delivery. The previously described mixed methods

Figure 2. Clinician Platform
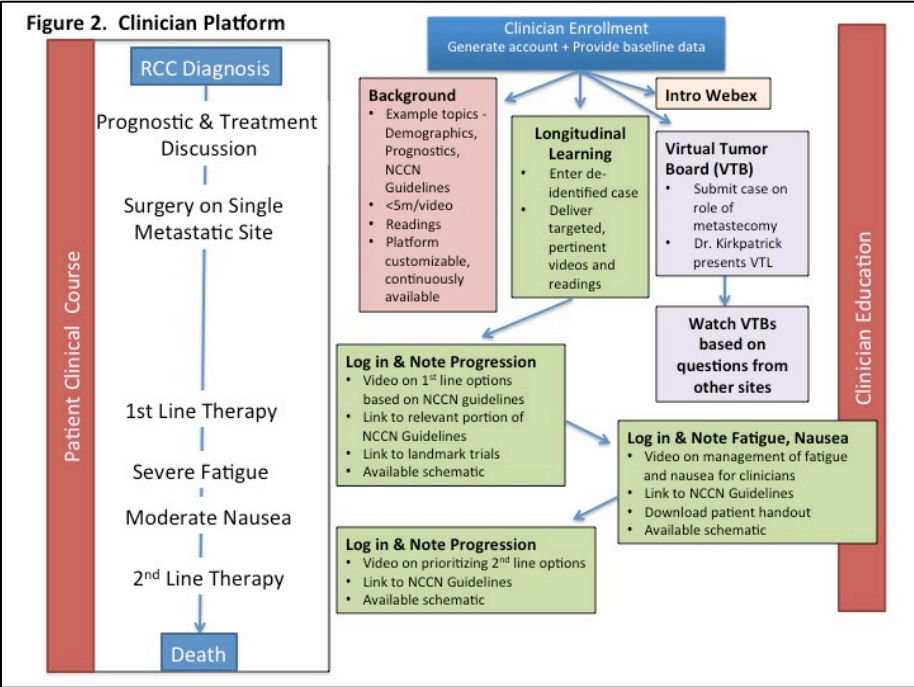
approach under the PRECEDE-PROCEED framework for health education program design will optimize platform design and usability. Traditional hour long, didactic lecture formats are avoided because they fail to meet the needs specific to the clinician using the system from both a time management and relevance perspective. Instead, clinicians will have multiple paths available to address learning needs as shown in Figure 2.

- **Sign up:** At initial login, the clinician will generate an account that will be accessible throughout the course of the study, enable alignment with their needs, and document their CME credits. Each clinician will begin by answering a short survey about their practice and their level of expertise with RCC. This will be matched to retrospective data.
- **Background Learning:** The clinician will have the opportunity to access various resources that cover high yield, targeted areas of interest related to the management of RCC. This is anticipated to include updates on RCC patient populations (e.g. demographics), treatment patterns in the community derived from our registry insights and national practice patterns, updates on NCCN treatment guidelines, common AEs and the management thereof, and a discussion of the most recent literature on these topics. Each will consist of concise videos, no more than 5 minutes each. These will be optional, continuously available, and aligned based on the pre-assessment learning.
- **Guidance Throughout Treatment Course:** More novel is the longitudinal coursework. This will be a responsive learning offering that is the core of the platform in which a clinician will provide de-identified data on a specific patient case (e.g., age, prior therapies, MSKCC/Heng risk). These data points will then be used to generate a longitudinal offering for the clinician on topics as they arise during the patient's course including baseline considerations, treatment options from the NCCN guidelines placed in clinical context, management of AEs, and other support structures. Figure 1 outlines an example. Participants will be able to revisit the curriculum as issues arise, reinforcing learning and going far beyond traditional CME offerings.
- **Additional Educational**: Since individuals may learn best in a variety of ways, the same content will be available in text formats with the visualizations designed for the video based offerings leveraged along with the didactic content. This avoids the need for note-taking and allows clinicians references that fit their needs.

B. Virtual Tumor Boards: While guidance specific to the treatment course of a given patient is highly beneficial, it is inadequate alone. Often patients do not meet the strict confines of traditional clinical guideline frameworks due to a variety of factors such as co-morbidities, histologic ambiguity, and secondary tumors. At Duke, these cases are addressed via tumor boards in which all of the relevant clinicians convene on a monthly basis to discuss challenging cases. Sometimes these tumor boards happen spontaneously in our multidisciplinary clinical practices as, for example, the urologic surgeon and GU medical oncologist literally work side by side seeing patients. Unfortunately, this expertise is not always available to clinicians at practices in the community. To address this shortcoming, we will hold 10 virtual tumor boards in which participating clinicians will have the opportunity to submit complex patient cases via email. The cases will be reviewed by Dr. Hirsch and the four most pertinent cases will be chosen for each session. As with traditional tumor boards, each case will begin with a summary of the patient case, including viewing of de-identified pathology and images. For each tumor board,

medical oncology, radiation oncology and urology will be represented from among the Duke faculty, at a minimum. A commentary relevant to the case will be presented prior to opening the floor to discussion. The cases will cover both challenging areas within RCC management and new insights. For those unable to attend, the sessions will be archived and available for later viewing with annotation to allow identification of portions of interest.

C. Patient Education Gateway: The final, and most novel, aspect of this work will focus directly on the patient. While a great deal of effort is spent educating clinicians, patients are often overlooked. Our approach will attempt to overcome this shortcoming. The project will leverage

Figure 3. Example of patient site developed by CLHC

extensive prior experience within the CLHC in patient-facing endeavors such as the Familial Hypercholesterolemia (FH) Registry (cascadefh.org) which is being conducted in collaboration with the FH Foundation (Figure 3) in which patients complete surveys about their disease and experience throughout the course of their illness in order to develop real world understanding of outcomes and QOL, while also pushing targeted education back to patients. This depth of experience with both information technology strategies and patient engagement will avoid the learning curve otherwise encountered with an endeavor such as this and ensure timely execution. A critical, yet often overlooked aspect of these endeavors is that the user interface and user experience are critical as clinicians and patients will not utilize the platform if it is not engaging. The FH Registry is just one example of the many projects within the CLHC focused on patient engagement activities such as our leadership within the NIH Collaboratory and PCORNet patient strategies. This expertise will enable us to design a complex, yet intuitive offering as represented in Figure 4.

- **Sign up**: While there are patient facing resources for those with RCC, the offerings are disjointed and incomplete. Many resources do not meet the varied learning needs of patients depending on factors such as demographics and education levels. As a result, clinicians at the proposed practices have agreed to provide information about the portal and to encourage participation with their patients. An in-person consent process will not be required as no intervention will occur beyond the delivery of IRB-approved patient education materials. However, basic patient identifiers will be captured at initial portal enrollment in order to track patient participation throughout the course of their disease. This will be achieved via an IRB-approved consent form that will be presented and accepted during enrollment. The CLHC has precedent with prior patient facing registries for this approach.

- **Background Teachings:** Evidence shows that patients do not have adequate insight into the nature of their disease. This can be blamed on numerous factors, one of which is a lack of reliable sources of education. After generation of the account, patients will see a background section that includes key components such as demographic information, an overview of staging, discussions of treatment modalities (e.g., surgical removal of metastatic sites, radiation, targeted agents, chemotherapy), prognostic considerations and the role of multi-disciplinary teams. While many such topics are predefined based on gap analyses and prior registry experience, the pre-assessment and thought leadership components will ensure adequate coverage.
- **Longitudinal Teachings:** While patients can revisit the baseline information throughout the course of their therapy, we hypothesize that longitudinal interactions throughout the patient's course will be higher yield and will drive retention of information and reuse of the system. After entering baseline information, patients will be able to return throughout the course of their disease to

Figure 4. Patient Platform
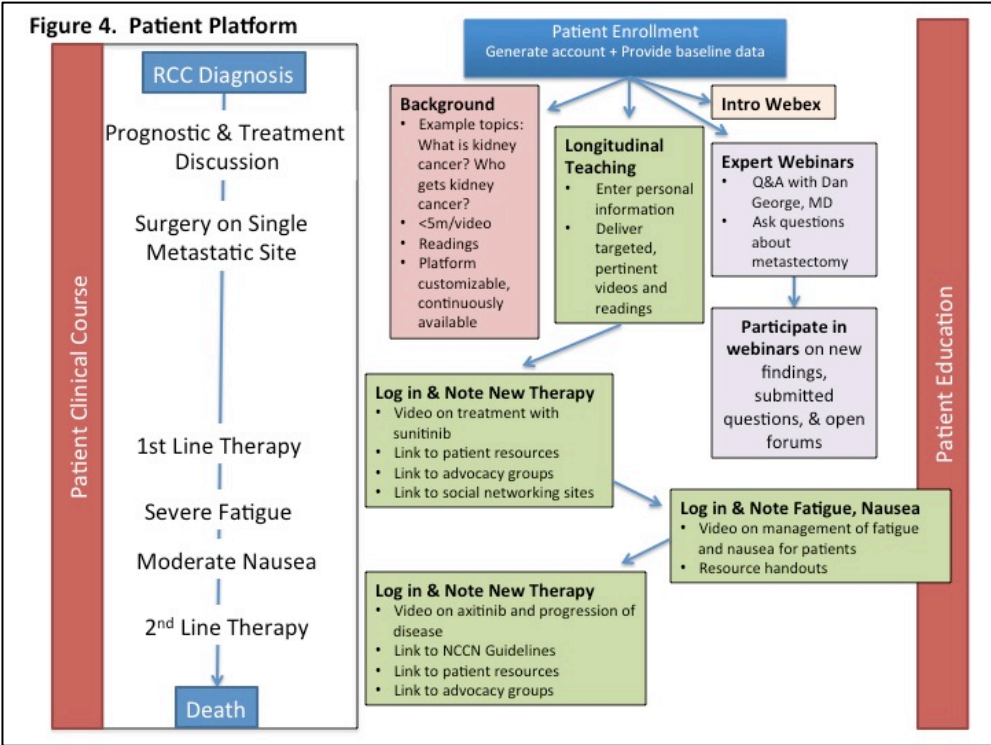
access timely information on a variety of topics such as treatment approaches (e.g., discussion of first line treatment considerations), recommendations regarding management of common AEs (e.g., fatigue, nausea, and hand foot syndrome), and provision of psychosocial support components.
- **Handouts –** The teachings provided in the interactive videos will also be converted to text documents that can be downloaded, acknowledging the varied learning habits of patients.
- **Informational Webinars and Q & A Sessions –** The final component will consist of monthly webinars led by the thought leadership on topics that are solicited from the participants, new research findings, and question and answer sessions. We anticipate ten of these offerings during the course of the project.

2.2.3 - Stage Three: Evaluation Design - Changes in provider knowledge, competence and performance will be assessed, as will patient and caregiver knowledge, satisfaction with care, and outcomes. Outcomes for the project will meet four Moore's levels: Learning (Level 3a, 3b), competence (Level 4), individual performance (Level 5), and patient health outcomes (Level 6).

- **Knowledge Evaluation**: HCP surveys will be conducted (pre and post) to assess baseline knowledge and acquisition of knowledge after the intervention on topics including diagnosis, treatment, AE management, and attitudes towards/barriers to patient care. This will augment previously performed analyses to ensure alignment. The direct pre/post-intervention comparison will provide a statistical efficacy measure with which to gauge the utility. Patient and caregiver surveys will be conducted (pre and post) to similarly assess baseline knowledge and acquisition thereof. It will be integrated with PRO data to assess impact on QOL metrics.

- **Learner Reaction Evaluation**: Assessments of the learner experience (i.e., satisfaction, frequency of utilization, feedback on opportunities for improvement) for both the physician- and patient-facing portals will be conducted. Semi-structured interviews of a subset of physicians and patients will provide additional granular detail about the learner experience, in order to inform platform optimization in a dissemination phase.

- **Outcomes Evaluation:** Through the established Duke/ACORN database, granular data are available on key metrics. This provides an ideal baseline to assess system improvement from this program. Because of the mixture of prevalent and incident cases, patients will be captured across the treatment paradigm thereby providing robust data for analysis looking at changes to newly diagnosed patients and those at various timepoints. The outcomes will include change in rate of guideline adherence, time on therapy at optimal dose, time to progression, AE rates, and QOL. PRO data will be a key analytic component. Data will be collected at baseline and at 6, 12 and 18 months of follow up as available. The data aggregation at DCN and ACORN will require an element of manual abstraction for those aspects not captured. Both sites have extensive experience with abstraction as part of the retrospective project and much of the data is already populated, significantly limited the degree of abstraction needed and the involved learning curve. The same CRF will be used, although pared down to specifically assess patient demographics, treatment sequence, time on therapy, progression intervals, QOL based on AEs, and the management thereof. Overall survival will not be assessed as the timeline for this project is limited.

- **Virtual Tumor Board Assessment:** The tumor boards will be evaluated for effectiveness via a tumor board evaluation scorecard used by facilitating faculty. This scorecard will be used to assess the success of this educational format to teach HCP about appropriate care.

2.3 – Data Analysis and Reporting - Completion of any part of this program will result in CME credits dependent on the amount of involvement. DukeCME will submit this quality improvement and educational program to the American Board of Medical Specialties to seek qualification for Part 4 of Maintenance of Certification (MOC). Since this should qualify for MOC credit, there will be significant clinician motivation to participate.

We will contract with Haymarket Media to assist with dissemination of the program at its completion. They will provide access to over 10,000 clinicians through a banner on the MyCME site, via initial and periodic email blasts to their medical oncology, radiation oncology,

urology, and Duke oncology listserves. They will also perform an initial marketing push at launch with periodic boosts as needed to maximize participation. We feel that is approach maximizes successful dissemination and would be augmented with further internal funding.

The proposed program will be readily usable by other healthcare systems and the results will be published in top-tier scientific journals. A series of e-news briefs will also be published online after completion of the program which will allow for the results of the analysis to be shared with national audiences. Deliverables will also include (1) a description of challenges and barriers encountered, (2) data on the practical ability to implement in a given health care system or setting, (3) the impact on patient level outcomes and relevant metrics such as time on therapy. The technology solutions to engage clinicians and patients and deliver the education will be scalable and afford a national reach.

2.4 Platform Design and Execution: Dr. Hirsch and Mr. Monroe will led the technology execution, with Mr. Park serving as the Project Manger. This team has extensive history working together within the CLHC. In an assessment of the marketplace, the conclusion was reached that no available platform exists to adequately meet the needs of this project. Instead, the team will utilize a web designer, programmer and videographer within the CLHC to adapt the patient engagement systems previously developed within the CLHC to the meet the needs of this program. The Education Gateway will be made to interface with the Learning Management System at the CEE to track and generate CMEs to avoid duplication.

3. Work Plan and Deliverables Schedule: Per the RFP, this endeavor is proposed over a 2 year timeframe, broken into 8 quarters. After announcement of funding, **Q1** would focus on program design and overall leadership. Outreach would be completed, appropriate contracts finalized, and the related build out would commence. From **Q1 to Q2**, three parallel processes would occur. Dr. Scales and the CEE group would collect the requisite baseline data for analysis and the pre-intervention assessment (stage 1) would take place. Simultaneously, the CLHC team and Kevin Monroe would utilize established infrastructure to build out the technology platform with both the clinician- and patient-facing portals. This would be overlaid within the LMS system to ensure that CME could be captured. Finally, the thought leadership team would complete the design, filming, and writing of the educational components. Since the three represent independent workflows, we believe that the timeframe is quite feasible with which to complete the related work. Dr. Hirsch and Michael Park would coordinate across the efforts.

The focus would switch from **Q3 to Q7** to active participation in the project implementation at DCN and ACORN sites. Michael Park would coordinate the effort in conjunction with the network liaisons. Dr. Hirsch and the team would closely monitor impact and utilization, responding as necessary to system feedback, provide advice as to optimization of the care content, and address difficulties with accrual and retention. At the same time, monthly virtual tumor boards would take place for clinicians and webinars for patients as described prior.

During **Q7 and Q8**, post intervention activities will take place including limited abstraction of patient data and analysis of results. Manuscript preparation and dissemination planning would be completed in **Q8** in conjunction with the CLHC, DCI, and Haymarket teams.

D. Organizational Detail

Duke Center for Learning Health Care (CLHC): The CLHC started as the Duke Cancer Care Research Program (DCCRP), focused on cancer symptom control clinical trials, cancer registries, PROs, data collection solutions, and integration of lessons learned into the day-to-day conduct of cancer care. As the portfolio of work grew, DCCRP expanded its focus to become Duke's CLHC. Through its work, the CLHC functions as a flagship initiative to develop and demonstrate methods that will support the model of a "rapid learning" clinic, and ultimately a learning health care system. The mission of the CLHC is "is to define, demonstrate, refine, and disseminate new methods of cancer care that best meet the needs of the individual patient."

CLHC's flagship work is in oncology and supportive care, although the approach is applicable across health care disciplines. The CLHC comprises six faculty members along with their associated clinical and research staff, numerous active collaborators, and oncology and palliative medicine fellows who train with the CLHC annually. Relevant to this application, the CLHC conducts a large portfolio of projects designed to generate evidence-based solutions to evidence gaps confronting cancer patients and clinicians in order to improve the quality of life and outcomes of patients. The portfolio features the use of information technology-based approaches to engage patients and providers to disseminate research insights.

The CLHC has a track record for conducting methodologically rigorous CME projects at Duke, nationally, and internationally. Operating procedures standardize all processes, and are fully disseminated to team members. The CLHC interfaces closely with the Duke University Health System Institutional Review Board (IRB), and all CLHC personnel are appropriately trained in Human Subjects Research, with credentials documented and updated annually.

Duke Center for Educational Excellence (CEE): The Center for Educational Excellence (CEE) was created at the DCRI with the *Vision* "to be the leader in medical education that enables excellence in clinical care and promotes patient safety". The *Mission* of DukeCME is *"to assist practicing physicians, pharmacists, advanced practice providers, and other health care professionals in the translation, diffusion, and application of evidence-based knowledge in appropriate formats to enhance clinical outcomes and improve patient safety."* The Duke Office for CME (DukeCME) also sits within the Duke Clinical Research Institute (DCRI), creating a critical partnership that facilitates the ability to develop and analyze educational programs that are designed to optimize Health Care provider performance, improve patient care and population outcomes.

DukeCME is accredited by the ACCME with commendation for excellence in educational program delivery and analysis. In FY 2012, DukeCME, certified over 4200 sessions within 228 separate educational programs. It provided 9514 hours of instruction to 45,640 physicians and 45,265 non-physician Health Care providers across a wide range of therapeutic areas for a total of 204,144 CME credits.

Duke CEE has considerable experience developing innovative web based platforms for education. Examples include the Physicians Executive Leadership Program, a mobile enabled web-based platform for business of medicine education; Duke TV / Duke Clinical Medicine Series; CTN Best Practices, a widely used central resource dedicated to providing tools and training for clinical researchers; and Centers for Education & Research on Therapeutics (CERTs),

a public-private partnership aimed at increasing awareness of the benefits and risks of therapeutics through education and research as supported by the Agency for Health Care Research and Quality (AHRQ)

DukeCME and its Associate Dean (Dr. Subramanian, a faculty of this program) will provide the organizational structure for the CME credit to be awarded only after approval of a CME application. In general, CME credit is awarded for 1) for each of the web-based/mobile program courses by the hour, 2) credit for the time spent on the worksheets/handouts and toolkits linked to the web-based courses, and 3) for involvement in virtual tumor boards to a predefined total CME credit allowable.

Duke Clinical Research Institute (DCRI): The DCRI is the parent organization to both the CLHC and CEE. The DCRI, as the world's largest academic research organization (ARO), has over 20 years of experience conducting innovative educational projects in addition to executing clinical research projects and is uniquely positioned to facilitate the creation and delivery of the live, mobile and web-based educational content for this program. Founded by a group of clinical and biostatistical researchers in 1969, the DCRI has grown into a >1,200 member organization committed to delivering efficient, high-quality programs that answer critical questions.

Duke Cancer Institute (DCI)

The DCI is a National Cancer Institute (NCI)-designated Comprehensive Cancer Center and is one of the most established cancer centers in the US and has been continuously funded by the NCI since initiation of its cancer center core grant program. The DCI draw from over 285 members from 23 basic and clinical departments within five schools at Duke University (Schools of Medicine, Nursing, Arts and Science, Engineering, and Divinity), providing great depth of clinical and scientific knowledge to draw from. The DCI is a single, multidisciplinary entity that integrates and aligns cancer-related patient care and research with goals to improve patient outcomes, accelerate scientific progress, and create leadership that promotes communication, accountability, and transparency across Duke Medicine.

ACORN Research, LLC

ACORN, a close collaborator of Dr. Hirsch and Duke's CLHC, is a multifaceted research organization that harmonizes a network of committed oncology research sites supported by centralized research processes, a bioinformatics platform that integrates EMR data with patient reported data to support health outcomes research and educational endeavors, and a Contract Research Organization focused exclusively on oncology. ACORN aggregates data collected from its clinicians by mapping electronic medical records (EMRs) from individual medical practices to a common platform, the ACORN Data Warehouse. As with the retrospective projects, this data can then be easily mined for the clinical variables of interest. The infrastructure includes medical oncologists, doctoral level scientists, statisticians, nurses, and a diverse professional staff with many years of oncology specific research experience. The ACORN team has an exceptional understanding of oncology from the perspectives of both the oncology sites and the sponsors.

Duke Cancer Network (DCN)

The DCN brings Duke's strengths in clinical care and research to local community practices. The DCN resources the technical and clinical expertise of Duke to enable communities throughout the eastern United States to provide an expanded array of patient-centered oncology services. In partnership with local, community-based organizations, the DCN provides oncology clinicians to 5 underserved communities in North Carolina and access to Duke investigator initiated clinical trials at its affiliates. While there are 20 affiliates with varying levels of involvement, the priority sites have been included in this proposal. Recent educational activities at the DCN have included formal on-site didactic lectures, participation in Tumor Conferences by disease experts, web-based curricula, and web-based journal club discussions. None have been specific to RCC. The DCN research team based at Duke consists of 2 regulatory specialists, 2 nurse coordinators dedicated to support of the network clinical sites, a Research Manager, and a Director of Research who serves on the management team for DCN. All affiliations include a research component with more than 560 subjects enrolled in clinical trials at these sites over the past three years.

Haymarket Medical Education

Haymarket Medical Education's (HME's) mission is to produce and deliver timely, scientifically rigorous, evidence-based, and innovative medical education that supports health care professionals' efforts to improve the quality of patient care. HME, in collaboration with accredited providers from academic institutions and specialty organizations, scales clinically CME programs that are relevant and practical in day-to-day clinical practice. Each year, HME collaborates on more than 200 educational programs in "live," electronic, and print formats with a combined reach of nearly 750,000 physicians, nurses, pharmacists, physician assistants, and nurse practitioners every month worldwide.

Staff Capacity

The Directors and Faculty for this program recognize the absolutely essential requirement to engage a committed full time project manager to appropriately, effectively and efficiently create and deliver this program in a timely manner. A Project Manager has been chosen for this project (Michael Park, MMCi) with therapeutic expertise in oncology paired with an informatics background in order to facilitate its execution. Key faculty and staff members will be organized by Mr. Park across the aforementioned entities. He sits within the CLHC and will identify a 'go to' person in each of the aforementioned groups (CLHC IT, CEE, DCN, and ACORN). He will have responsibility to ensure that the timelines are being met across involved parties and will be responsible for engaging the DCN and ACORN Liaison manager to ensure that the program is delivered effectively to the community-based practices. It would be expected that the Project Manager would be flexible and accountable to increase and add responsibilities as they are identified to effectively manage this program. This grant will also incorporate specific DCN and ACORN program management for the community engagement, coordination of grant-related activities (e.g. focus groups, post-intervention coaching, data abstraction, etc.). These individuals will coordinate both the identification of RCC patients and chart data abstraction. Mr. Park will also facilitate setting up the educational opportunities for providers that are convenient to each practice.

Appendix 1. Project Timeline

Activity Phase	Action	Proposed Timing after Project Award
Planning	Site/Faculty Recruitment & Contracting	Q1
Planning	Education Gateway Completion	Q2
Planning	Education Content Completion	Q2
Assessment	Completion of Pre-Intervention Assessment	Q3
Implementation	Site Initiation, Intro Webinars	Q4
Implementation	Interim Assessment of Impact	Q6
Conclusion	Evaluation Assessment	Q7
Conclusion	Data analysis and Best Practices writing	Q7
Conclusion	Manuscript Preparation, Reporting and Finalization of Dissemination Plan	Q8

Appendix 2. References

1. Harrison MR, George DJ, Walker MS, et al. "Real world" treatment of metastatic renal cell carcinoma in a joint community-academic cohort: progression-free survival over three lines of therapy. *Clinical genitourinary cancer.* Dec 2013;11(4):441-450.
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March 5, 2014

Bradford Hirsch, MD, MBA
Director, Clinical Informatics and Learning Laboratories
Duke Center for Learning Health Care
Duke Clinical Research Institute
2400 Pratt Street, Durham, NC 27705

Re: Novel Educational Interventions for Community Oncologists and Patients:
Optimizing Renal Cell Carcinoma Outcomes through Engagement

Dear Dr. Hirsch:

The Duke Cancer Network (DCN) is excited to partner with the Center for Learning
Health Care and the Center for Educational Excellence to implement the novel
educational platform that is being developed for RCC patients and their clinicians. The
DCN provides a single collaborative group to bring the strengths of Duke into local
community practices. In partnership with community-based organizations, DCN provides
oncology clinicians to 5 rural, underserved communities in North Carolina. The DCN has
experience with the provision of CME supported educational activities in a variety of
formats however the focus and mechanism proposed herein would be unique.

DCN's 5 sites included 7 clinicians who treated 39 renal cell patients in 2012, providing
access to an ample number of participating clinicians and patients who could benefit from
these novel educational interventions. We support the creation of the platform to improve
stakeholder understanding of this disease, to facilitate the exchange of ideas, and to
optimize treatment outcomes. The integration of the DCN into the planning of this
platform will help to maximize the likelihood of a workable solution across sites.

As Medical Director of the DCN, I am well positioned to advise the CLHC in building
this platform to support our network of sites. DCN is very enthusiastic to begin working
on this project as we see it as a way to engage RCC clinicians and patients in quickly
advancing the understanding of this devastating disease.

Sincerely,

Linda M. Sutton, MD
Medical Director
Duke Cancer Network

ACORN Research, LLC
An Optimized Platform for Precision Oncology

March 5, 2014

Bradford Hirsch, MD
Director, Clinical Informatics and Learning Laboratories
Duke Center for Learning Health Care
Duke Clinical Research Institute
2400 Pratt Street
Durham, NC 27705

Re: Novel Educational Interventions for Community Oncologists and Patients:
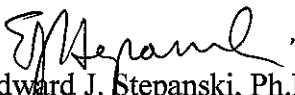Optimizing Renal Cell Carcinoma Outcomes through Engagement

Dear Dr. Hirsch:

ACORN is excited to potentially partner with the Duke Center for Learning Health Care
(CLHC) and the Duke Center for Educational Excellence to test novel educational
interventions for community oncologists and patients to improve quality of life and
outcomes for renal cell patients. This collaboration is a continuation of our ongoing,
fruitful work with the CLHC conducting an extensive retrospective review of real world
renal cell carcinoma practice patterns since 2007. Lessons learned from this observational
study will inform the creation of the educational offerings described in this proposal.
Furthermore, ACORN's nine sites which included 76 clinicians and 232 renal cell
patients in 2013 will potentially provide an excellent testing ground for these novel
educational programs.

We support the creation of this platform dedicated to engaging clinical oncologists and
patients to improve their understanding of this disease, facilitate exchange of ideas, and
optimize treatment outcomes. While we do not directly manage the sites, if funded, we
will facilitate engagement with them.

As Chief Operating Officer at ACORN, I commit to assisting with alignment between
Duke and the associated study sites. ACORN is very enthusiastic to begin working on
this project as we see it as a way to engage RCC clinicians and patients in quickly
advancing the understanding of this destructive disease.

Sincerely,

Edward J. Stepanski, Ph.D.
Chief Operating Officer
ACORN Research

March 6, 2014

Bradford Hirsch, MD, MBA
Director, Clinical Informatics and Learning Laboratories
Duke Center for Learning Health Care
Duke Clinical Research Institute
2400 Pratt Street, Durham, NC 27705

Re: Novel Educational Interventions for Community Oncologists and Patients: Optimizing
Renal Cell Carcinoma Outcomes Through Engagement

Dear Dr. Hirsch:

I am writing to you to convey my complete support for your grant proposal: "Novel Educational
Interventions for Community Oncologists and Patients: Optimizing Renal Cell Carcinoma
Outcomes Through Engagement."

The Duke University School of Medicine, Office of Continuing Medical Education is the
professional educational arm of the Duke University of School of Medicine. As Assistant Dean
and Director of Duke Continuing Medical Education, I am pleased to ensure Duke CME's full
support for this important initiative designed to achieve improved renal cell carcinoma (RCC)
management and outcomes.

Sincerely,

Chitra Subramaniam, PhD
Assistant Dean and Director, Duke Continuing Medical Education
Asst. Director Center For Educational Excellence
Duke Clinical Research Institute
300 W Morgan Street
Durham, NC 27701
(919) 401-1205
chitra.subramaniam@duke.edu

Duke Cancer Institute

March 5, 2014

Bradford Hirsch, MD
Director, Clinical Informatics and Learning Laboratories
Duke Center for Learning Health Care
Duke Clinical Research Institute
2400 Pratt Street, Durham, NC 27705

Re: Novel Educational Interventions for Community Oncologists and Patients:
Optimizing Renal Cell Carcinoma Outcomes through Engagement

Dear Dr. Hirsch:

The Duke Cancer Institute (DCI) looks forward to partnering with the Center for
Learning Health Care in building the content for this innovative educational
platform through an interdisciplinary collaboration among medical oncology,
urology, radiation oncology, and pathology. These specialties already work
together extensively through multidisciplinary clinics and tumor boards within the
DCI, so there is clear precedent for this project.

As director of DCI's genitourinary cancers program, I welcome collaborations
with professionals researching all genitourinary cancers including renal cell
carcinoma. I believe this platform will allow our clinicians to share their
knowledge and learn from clinicians and patients at all of the other sites engaged
with this educational solution. After we demonstrate the effectiveness of the
platform with renal cell carcinoma, I foresee this platform be leveraged across all
malignancies treated and studied at the DCI. Educating our medical oncologists
and patients is important to improving outcomes across all cancer types, but
especially with cancers such as renal cell carcinoma where individual clinicians
may seem limited patient volumes.

I look forward to supporting you as you develop this project as it promises to be
an effective tool to engage our RCC clinicians and patients and improve our
understanding of this destructive disease.

Sincerely,

Daniel J. George, MD
Director, Genitourinary Oncology
Duke Cancer Institute

March 7, 2014

To: Bradford Hirsch, MD, MBA
Duke Cancer Institute
Director, Clinical Informatics & Learning Laboratories
Center for Learning Health Care
Duke Clinical Research Institute

Dear Dr. Hirsch,

I am pleased to offer my support for your proposed research project entitled "Novel Educational Interventions for Community Oncologists and Patients: Optimizing Renal Cell Carcinoma Outcomes Through Engagement" in response to the National Cancer Center Network and Pfizer Independent Grants for Learning & Change proposal request.

Development of the proposed educational platform and assessment of the intervention's impact will be a substantial step forward in the care of patients with renal cell carcinoma. Given the relatively low volumes of patients with renal cell carcinoma in community oncologic practice, creation of this innovative educational resource will improve clinicians' knowledge, competence and skills. In addition, the novel addition of a patient-facing portal will improve quality-of-life for patients and caregivers.

As a health services researcher, educator and practicing urologist, I am well positioned to collaborate on this proposal. During my time at the Robert Wood Johnson Foundation/VA Clinical Scholars Program at the University of California, Los Angeles, I received formal training and experience in community-engagement strategies and program evaluation. In addition, I have extensive experience with secondary analyses of existing datasets, which will be key to the success of the project. Specifically, I will lead the initial assessment stages of the project under the PRECEDE-PROCEED framework to maximize uptake and sustainability of the educational intervention.

I look forward to working with you on this important effort to improve care for patients with renal cell carcinoma.

Sincerely,

Charles D. Scales, Jr. MD MSHS
Assistant Professor of Surgery
Division of Urology

Diane L. Bloom, MPH, PhD
Qualitative Research Consultant
114 Mendel Drive, Chapel Hill, NC 27514

March 7, 2014

To: Bradford Hirsch, MD, MBA
Duke Cancer Institute
Director, Clinical Informatics & Learning Laboratories
Center for Learning Health Care
Duke Clinical Research Institute

Dear Dr. Hirsch,

Thank you for inviting me to serve as a consultant on your proposed research project entitled "Novel Educational Interventions for Community Oncologists and Patients: Optimizing Renal Cell Carcinoma Outcomes Through Engagement." I write this letter to communicate my enthusiastic support for and commitment to this important and timely project.

I would be pleased to provide assistance planning, organizing, collecting, and analyzing qualitative data from patient and clinician in-depth interviews for this study. I understand that this qualitative piece is part of a larger mixed-method study that seeks to better understand the needs of RCC patients and their physicians, as well as to identify systems-level gaps. Information from these interviews will be used to tailor novel educational tools and platforms to the needs and preferences of both of these audiences, with the ultimate goal of more optimal renal cell carcinoma management and improved outcomes for patients with this disease.

For more than 20 years, I have been a qualitative researcher specializing in project planning and design in the healthcare field and in conducting and analyzing in-depth interviews and focus groups across a broad range of health topics. My work has ranged from patient and physician needs assessment, to evaluating and pretesting communications materials, to analyzing the way the patients make healthcare treatment decisions. I have done extensive research in the area of cancer treatment and decision-making, and am well versed in the Precede-Proceed framework of health-education program planning. One of my strengths is designing discussion guides to obtain a deeper level of thinking and insight. I have taken workshops at the Creative Problem Solving Institute (CPSI), The Tavistock Institute, and the Qualitative Research Consultants Association to enhance these skills. I have taught Qualitative Research Methods to doctoral students at the School of Public Health at the University of North Carolina at Chapel Hill, and I conduct training workshops around the country on how to plan and conduct successful qualitative projects. I have received two NIH Plain English Awards for report writing.

My plans are to work with you and your team to organize and moderate in-depth interviews with oncologists and patients with RCC. After data collection, I will analyze the qualitative data and write a comprehensive report of the findings.

I look forward to working with you on this important effort to understand patient and physician needs.

Diane Bloom, MPH, PhD
bloom.diane@gmail.com
919-201-9975