AWARD NUMBER: W81XWH-21-1-0731

TITLE: Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses

PRINCIPAL INVESTIGATOR: Robert Motzer

CONTRACTING ORGANIZATION: Sloan Kettering Institute for Cancer Research
New York, NY

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PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

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4. TITLE AND SUBTITLE

Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses

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5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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Robert Motzer, Robert Goodman, Alisa Ritea, Cindy Puzio

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Sloan Kettering Institute of Cancer Research
1275 York Ave
New York, NY 10065

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U.S. Army Medical Research and Development Command
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12. DISTRIBUTION / AVAILABILITY STATEMENT

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

During the review period, investigators and mentors are credited in initiating a renal cell cancer clinical research nurse-specific training and orientation program for three clinical research nurse trainees. We have also mentored the clinical research nurse trainees in the beginning stages of the research project.

15. SUBJECT TERMS Clinical trial nursing, Training, Telemedicine					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified	Unclassified	24	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Clinical trial development has been critical for improving the outcomes of patients with kidney cancer, with the approval of 13 new treatments in the last 15 years. With proper oversight, clinical trials provide patients safe, early access to new medications that are promising. However, access to these novel treatments can be limited by the availability of expertise. Clinical research nurses (CRNs) are critical members of the patient's medical team that ensure that new medications can be delivered ethically, safely, and effectively. We hypothesize that having CRNs that are specialized in kidney cancer will improve the safety and tolerability of patients treated on clinical trials by improving the management of side effects and making sure patients adhere to the schedule and rules of the clinical trial.

To improve the access of disease-specific CRNs, we propose a project with two specific aims:
Specific Aim 1: Establish a kidney cancer–specific CRN training program
Specific Aim 2: Perform a pilot project to study the safety and quality of care when integrating telemedicine into clinical trial nursing

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Clinical trial nursing, Training, Telemedicine

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Specific Aim 1: To establish a kidney cancer-specific fellowship program for CRNs

- Major Task 1: Train and orient CRN trainees who have limited experience in management of kidney cancer patients in research setting
- Major Task 2: Educate CRN trainees on kidney cancer pathophysiology, disease and symptom management, clinical research nursing practice, nursing research, and clinical trial operations

Specific Aim 2: To conduct a pilot research project providing research training experience to CRNs

- Major Task 1: Train and orient CRN trainees and CRA
- Major Task 2: Collection of safety and protocol compliance data from target populations

- Major Task 3: To compare healthcare utilization via outpatient and inpatient points of care before and after telemedicine adoption
- Major Task 4: To determine safety and protocol compliance as defined by rates of SAEs, rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption
- Major Task 5: To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Specific Aim 1:
- *Major Task 1:*
  - *Completed: Subtasks 1 – 18*
- *Major Task 2:*
  - *Completed: Subtask 1-9*

Specific Aim 2: We proposed to conduct a pilot research project providing research training experience to CRNs and collecting data on clinical trial patient participants that conducted telemedicine visits. This included collection of safety and protocol compliance data from our target population as well as patient and provider perceptions of telemedicine.
- *Major Task 1:*
  - *Partially Completed: Subtask 1-3*
  - We identified and trained a CRA for our research project and trained and oriented two CRNs.
- *Major Task 2:*
  - *Partially Completed: Subtask 1, 2, 3, 4 and 5*
  - We designed and generated a RedCap database for project data collection of patients, nurses, and providers enrolled in our telemedicine project. We have prospectively identified patients and providers for these cohorts and performed a retrospective chart review on demographic and clinical characteristics. This demographic and clinical information has been annotated on RedCap with 40 patients total. **Subtask #3** is ongoing as we plan to analyze data of patients designated for the Pre-Telemedicine Cohort as a matched-control sample.
- *Major Task 3:*
  - *Nothing to report*
- *Major Task 4:* We proposed to determine safety protocol compliance as defined by rates of serious adverse events (SAEs), rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption

- *Partially Completed: Subtask 1 & 3*
- determine rates of SAEs from patients in the Telemedicine Cohort. Specifically of the 40 patients enrolled in the pilot program, 9 patients experienced an SAE during the time they were monitored through telemedicine visits. We will plan to compare this with rates of SAE in matched patients in the Pre-Telemedicine Cohort. We will additionally analyze information on grade 3/4 toxicities and protocol deviations.

- *Major Task 5:* we proposed to compare patient and provider (physician and nursing) perceptions of telemedicine, and specifically as it relates to clinical trials participants.
  - *Completed: Subtask 1 and 2*
    - Generated distinct questionnaires for patients, physicians, and nurses and obtained IRB-approval (8/30/2022) to distribute these questionnaires (**Table 1)**. These surveys were distributed quarterly to patients enrolled in clinical trials during the pilot program and providers engaged in clinicals trials research and telemedicine visits.
    - **Table 1:** Completed Questionnaires

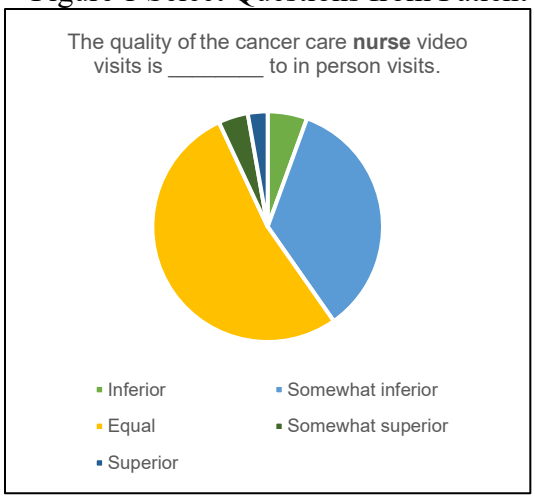
Participant Type	**Participant Number**	**Questionnaire Number**
Patient	40	72
Nurse	7	20
Physician/APP	15	39

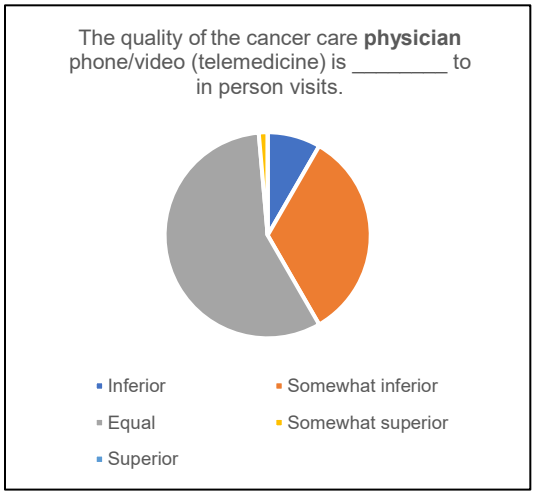
  - *Completed: Subtask 3 & 4*
    - Collected provider and patient perception data in 2023. Patients were offered identical questionnaires at three quarters during their telemedicine experience in 2023. These questionnaires consisted of three sections, which asked about baseline perceptions on telemedicine, specific perceptions on nursing encounters via telemedicine for clinical trials, and specific perceptions on physician encounters via telemedicine for clinical trials. A total of 40 patients completed 72 questionnaires; 32 patients completed 2 questionnaires and 8 patients completed 1. The median age of the 40 patients was 61 and 83% were White and only 5% were Black. Of these 40 patients, 100% had English as their preferred language. Patients were distributed across several lines of systemic therapy, including adjuvant (10%), first-line metastatic disease (43%), second-line (35%), and third-line and beyond (12%). Please see **Table 2** below for more details.
    - **Table 2**: Demographic and Clinical Characteristics of Patient Participants

Age – median (range)	61 years (43-82)
Male Sex, N (%)	34 (85%)
Race, N (%)	
White	33 (83%)
Black	2 (5%)
Other/Unknown/Refused to Answer	5 (13%)
Preferred Language, N (%)	
English	40 (100%)
Other	0 (0%)
Renal Cell Carcinoma type, N (%)	
Clear Cell	33 (83%)

Other	7 (17%)
Line of Systemic Therapy, N (%)	
Adjuvant	4 (10%)
First	17 (43%)
Second	14 (35%)
Third or more	5 (12%)

- Importantly, at baseline, patients expressed preferring in-person visits with nurses in 30 surveys (42%) and physicians in 32 surveys (44%), having no preference with nurses in 17 surveys (24%) and with physicians in 15 (21%), and preferred telemedicine with nurses in 12 surveys (17%) and with physicians in 13 surveys (18%). Approximately 17-18% expressed that their preference on in-person vs telemedicine depended on the type of care visit. In free text responses, patients expressed the convenience and flexibility of having both options. Patients considered themselves to be tech savvy in 35 surveys (49%). Patients were then asked questions specific to their clinical trial encounters with nurses and physicians. When asked about nursing, patients in 52 surveys (72%) felt that a telemedicine visit was equal or better in adequately managing care and patients in 43 surveys (60%) felt that a telemedicine visit delivered equal or superior quality care **(Figure 1)**. When asked about physician visits, patients in 47 surveys (65%) felt that a telemedicine visit was equal or better in adequately managing care and patients in 42 surveys (58%) felt that a telemedicine visit delivered equal or superior quality care **(Figure 1)**. Patients noted that in-person interactions allowed for a more thorough evaluation and visit.
- Figure 1 Select Questions from Patient Questionnaire





- Clinical research nurses were concurrently offered questionnaires at three different quarters during their telemedicine experience in 2023. A total of 7 nurses completed 20 questionnaires. These questionnaires consisted of two sections, which asked about baseline perceptions on telemedicine and specific perceptions on clinical trials research via telemedicine. In 18 surveys (90%), the nurses expressed preference for in-person visits for clinical trial participants and in 2 surveys (10%), there was no preference between in-person and telemedicine. They

specifically noted a better ability to assess adverse events and toxicities in person. Furthermore, in 17 surveys (85%), the nurses expressed that a telemedicine visit was worse in adequately managing care and delivered inferior quality care. They did note that their experience with telemedicine clinical trial participant visits was positive (50%) or neither positive nor negative (50%).

- Providers (physicians and advance practice providers) were also offered questionnaires at three different quarters during their telemedicine experience in 2023. A total of 15 providers completed 39 questionnaires. These questionnaires consisted of two sections, which asked about baseline perceptions on telemedicine and specific perceptions on clinical trials research via telemedicine. In 34 surveys (87%), providers expressed preference for in-person visits for clinical trial participants and in 5 surveys (13), they expressed no preference. They also noted a more thorough clinical assessment in-person. Furthermore, in 30 surveys (77%), the providers expressed that a telemedicine visit was worse in adequately managing care and in 34 surveys (87%) delivered inferior quality care. They did note that their experience with telemedicine clinical trial participant visits was positive (33%) or neither positive nor negative (51%) in most instances.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

CTN trainee 1, 2, 3 attending didactic lectures
CTN trainee 2, completed one on one mentoring
CTN trainee 1, 2 completed participation in research project, trainee 3 has ongoing participation in research project,
CTN trainee 1, 2, 3 participated in journal club and weekly clinical trial research meetings.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Research for specific aim 2 will be published in a manuscript describing the perceptions of telemedicine in clinical trial management

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Program participants (PI, CRN Mentors and CRN Trainees) were unable to complete funded travel due to staffing. Participants are frontline staff and, since the onset of COVID, we experienced staffing shortages and high patient volumes, limiting the ability for nurses to take time off. Therefore, we did not spend funds allocated for travel to conferences for continued education of Clinical Research Nurse (CRN). We requested and were approved for a No Cost Extension (NCE) to spend down our travel fund in 2024. PI has worked with CRN Mentor and Trainees to identify upcoming conferences and professional education seminars. We will complete this by end of NCE.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report

- **Other Products**

  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Name: Motzer, Robert
Project Role: PI
Researcher Identifier (e.g. ORCID ID): 0000-0001-6925-2327
Nearest person month worked: 1.8 CYM
Contribution to Project: Project methodology, supervision of analyses, project administration, supervision
Funding Support:

Name: Liang, Stanley
Project Role: Clinical Research Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 8.6 CYM
Contribution to Project:
Funding Support: data curation, suvery creation, database maintenance, project administration, and collating data

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Please see updated support documentation

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
<u>Organization Name:</u>
<u>Location of Organization: (if foreign location list country)</u>
<u>Partner's contribution to the project</u> (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ebrap.org/eBRAP/public/index.htm*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil/Pages/Resources.aspx) should be updated and submitted with attachments.*

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

Previous/Current Support
Motzer, Robert

PREVIOUS (Completed since 10/28/2022 Annual Report)
None

CURRENT

Newly Added Current Support:
None

Previously Report Current Support:
Title: Evaluating HLA Class II Evolutionary Divergence as an Immunotherapy Specific Kidney Cancer Biomarker (KC200127)
Role: Mentor
Sponsoring Agency: Department of Defense/Congressionally Directed Medical Research
Effort:

	Year (YYYY)	Person Months (##.##)
3.	2024	1.20 calendar
4.	2025	1.20 calendar

Level of Funding (Direct Costs):
Performance Period: 9/30/2021 – 9/29/2025
Name of Contracting/Grants Officer: Joshua D. McKean, Grants Officer
Contact Information for Grants Officer: joshua.d.mckean3.civ@mail.mil | 301-619-4046 | Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014
Project Goals/Specific Aims: The goals of this project are to 1) determine whether predicted neoantigens peptides to be presented by HLA class I and II alleles are enriched in clear cell compared to non-clear cell RCC variants ; 2) determine whether HLA class II allelic repertoires and divergence (HED) correlate with treatment outcomes in clear cell RCC patients treated with ICI therapies ; 3) determine whether HLA class I and II alleles and composite HED correlates with treatment outcomes in a non-clear cell RCC prospective clinical trial employing VEGFR TKI and immunotherapy.
Overlap Statement: None.

Title: Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses (KC200301)
Role: Principal Investigator
Sponsoring Agency: Department of Defense / Congressionally Directed Medical Research
Effort:

	Year (YYYY)	Person Months (##.##)
2.	2024	1.80 calendar

Level of Funding (Direct Costs):
Performance Period: 09/30/2021 – 09/29/2024 NCE
Name of Contracting/Grants Officer: Joshua D. McKean, Grants Officer
Contact Information for Grants Officer: joshua.d.mckean3.civ@mail.mil | 301-619-4046 | Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014
Project Goals/Specific Aims: We propose the development of a formal RCC CRN fellowship program to provide clinical training alongside RCC-specific mentorship, didactic lectures, and clinical and translational research training. CRN Trainees will be paired one-to-one with CRN and Physician Mentors during the fellowship, which will contain a clinical orientation phase, an education phase, and a research phase.
Aim 1: To establish a kidney cancer-specific fellowship program for CRNs
Aim 2: To conduct a pilot research project providing research training experience to CRNs
Aim 2a: To compare healthcare utilization via outpatient and inpatient points of care before and after telemedicine adoption

Aim 2b: To determine safety and protocol compliance, defined as rates of SAEs, rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption.
Aim 2c: To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs.
Overlap: None.

Title: Towards Precision Immuno-Oncology: Unraveling The Genomic Determinants and Mechanisms Underlying Immunotherapy Efficacy And Resistance
Role: Collaborator
Sponsoring Agency: National Cancer Institute (R35 CA232097)
Effort:

	Year (YYYY)	Person Months (##.##)
5.	2024	0.80 calendar
6.	2025	0.80 calendar

Level of Funding Amount (Direct Costs):
Performance Period: 5/1/2020 - 8/31/2025
Name of Grants Officer at Sponsoring Agency: Connie Sommers
Contact Information for Grants Officer: sommersc@mail.nih.gov
Goals/Specific Aims: The purpose of the MSK subcontract is to include Dr. Ming Li, Dr. Robert Motzer, and Dr. Michel Sadelain in this project. Dr. Li will collaborate for immune phenotyping and immune functional studies. Dr. Motzer will collaborate to study the mechanisms of immunotherapy response in patients with kidney cancer and other cancers with his experience in establishing new treatment paradigms. Dr. Sadelain will contribute to the analysis of immune cells, microenvironment analysis and analysis of T cell repertoire data as well as provide expertise, programmatic guidance, and laboratory reagents. Cleveland Clinic Lerner College of Medicine is the prime institution.
Overlap: None.

Title: Integrated Analysis of Somatic Genomic Mutations and Antigen Presentation as Predictive Biomarkers for Combination Immunotherapy in Kidney Cancer (KC190157)
Role: Career Guide
Sponsoring Agency: Department of Defense/Congressionally Directed Medical Research Programs
Effort: 0 CYM during NCE period
Level of Funding Amount (Direct Costs):
Performance Period: 9/30/2020–9/30/2024 NCE *pending approval of NCE request
Name of Grants Officer at Sponsoring Agency: Joshua McKean
Contact Information for Grants Officer: joshua.d.mckean3.civ@mail.mil | 301-619-4046 | Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014
Goals/Specific Aims: Aim 1, determine how tumor-specific mutations alter tumor mutation burden and the expression of mutated genes. Aim 2, determine the contribution of human leukocyte antigen diversity, tumor mutation burden, and somatic mutations as key components of tumor antigen burden and correlate tumor antigen burden to responses to nivolumab, tyrosine-kinase inhibitors and PD-1/PDL-1 inhibitors, and PD-1/PDL-1 and anti-CTLA-4 inhibitors.
Overlap: None.

Kotecha, Ritesh

Previous/Current Support

PREVIOUS (Completed since 10/28/2022 Annual Report)

*Title: Development of RNA Biomarkers for Real-Time Profiling and Therapy Stratification for Advanced Renal Cell Carcinoma Patients
*Major Goals: Aim 1: Evaluate RNA signatures as a treatment stratification tool for treatment metastatic ccRCC patients
*Status of Support: Previous
Project Number: ASCO YIA 9.23
Name of PD/PI: Khaleel, S
Source of Support: American Society of Clinical Oncology
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 7/1/2022 - 6/30/2023
*Total Award Amount (including Indirect Costs):
Grant manager: grants@conquer.org

Person Months (Calendar/Academic/Summer) per budget period.
No specified effort required

*Title: Human Leukocyte Antigen Evolutionary Diversity – A Population-Specific Biomarker for Kidney Cancer Immunotherapy
*Major Goals: To determine whether specific subtypes of localized and advanced RCC are more prevalent in different racial and ethnic subgroups.
*Status of Support: Active
Project Number: AWD-GC-260384
Name of PD/PI: Kotecha, R
Source of Support: Kidney Cancer Association
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 10/1/2020 - 9/30/2023 NCE
*Total Award Amount (including Indirect Costs):
Grant Manager: Stephanie Shirley, sshirley@kidneycancer.org

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2022	1.20 calendar

CURRENT

Newly Added Current Support:

*Title: Generation of Patient-Specific Humanized Mouse Models to Recapitulate Human Tumor Microenvironments for Optimal CAR-T Cell Therapy in Kidney Cancer
*Major Goals: Our goal in this proposal is to generate a more physiological animal model to develop CAR-T therapy for RCC. Our specific aims are:
Aim 1: To develop a patient-specific humanized clear cell RCC mouse model where the immune system, tumor and CAR-T cells are all derived from the same patient.
Aim 2: To evaluate CD70 CAR-T efficacy and toxicity in the patient-specific humanized mice established in Aim 1.

*Status of Support: Active
Project Number: DOD KCRP Concept Award (Log KC220154)
Name of PD/PI: Hanina, S
Source of Support: DOD - Department of Defense
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 10/1/2023 - 9/30/2024
*Total Award Amount (including Indirect Costs):
Grant manager: Joshua D. McKean, joshua.d.mckean3.civ@mail.mil

Person Months (Calendar/Academic/Summer) per budget period.
Year (YYYY) Person Months (##.##)
1. 2024 0.12 calendar

*Title: Molecular Classifications of Kidney Cancer by AI Machine Learning
*Major Goals: 1. Optimize identification of machine learning (ML)-based angiogenesis and myeloid transcriptomic signatures from RCC tumor pathology image slides using a convoluted neural network platform. 2. Determine whether ML-signatures are associated with recurrence-free survival (RFS) in renal cell carcinoma patients after nephrectomy. 3. Determine whether ML-signatures are associated with objective response (ORR) and progression-free survival (PFS) when treated with immune checkpoint blockade and VEGFR TKI therapy.
*Status of Support: Active
Project Number: MSKCC Society Kotecha
Name of PD/PI: Kotecha, R
Source of Support: MSKCC Society
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 1/1/2023 - 12/31/2023
*Total Award Amount (including Indirect Costs):
Grants Manager: Lauren Ferraioli, ferraiol@mskcc.org

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY) Person Months (##.##)
1. 2023 0.60 calendar

*Title: NFCR GRANT APPLICATION
*Major Goals: SPECIFIC AIMS:
1. Evaluate CTC capture feasibility and validity in metastatic RCC patients treated with systemic therapies.
a. Evaluate the CTC detection and yield rates and correlate with radiographic tumor volumetric data.
b. Perform matched NGS profiling of CTC and matched tumor tissues (primary nephrectomy or metastatic site) to determine concordance and clonality estimates.
2. Determine whether dynamic changes in CTC load and profile are associated with systemic therapy response in RCC patients. a. Perform baseline and on-treatment serial isolation of CTC to correlate longitudinal changes with objective response rates (via RECIST v1.1).
*Status of Support: Active
Project Number: National Foundation For Cancer Research
Name of PD/PI: Kotecha, R
Source of Support: National Foundation For Cancer Research
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 12/1/2022 – 8/31/2024
NCE
*Total Award Amount (including Indirect Costs):
Grants Manager: Hali Hartmann, info@nfcr.org

Person Months (Calendar/Academic/Summer) per budget period.
Year (YYYY) Person Months (##.##)
1. 2023 0.60 calendar

Previously Report Current Support:
*Title: Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses
*Major Goals We propose the development of a formal RCC CRN fellowship program to provide clinical training alongside RCC-specific mentorship, didactic lectures, and clinical and translational research training. CRN Trainees will be paired one-to-one with CRN and Physician Mentors during the fellowship, which will contain a clinical orientation phase, an education phase, and a research phase.
Aim 1: To establish a kidney cancer-specific fellowship program for CRNs
Aim 2: To conduct a pilot research project providing research training experience to CRNs
Aim 2a: To compare healthcare utilization via outpatient and inpatient points of care before and after telemedicine adoption
Aim 2b: To determine safety and protocol compliance, defined as rates of SAEs, rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption.
Aim 2c: To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs.
*Status of Support: Active
Project Number: W81XWH-21-1-0731
Name of PD/PI: Motzer, R
Source of Support: Kidney Cancer Association
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 09/30/2021 – 09/29/2024 NCE
*Total Award Amount (including Indirect Costs):
Grant manager: Joshua D. McKean, joshua.d.mckean3.civ@mail.mil

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY) Person Months (##.##)
1. 2024 0.60 calendar

*Title: Evaluating HLA Class II Evolutionary Divergence as an Immunotherapy Specific Kidney Cancer Biomarker
*Major Goals: We hypothesize that high HED amongst HLA class II alleles is associated with superior response and increased toxicities to ICI based therapies when compared to non-ICI therapies,
particularly when RCC tumors harbor neoantigens predicted to be displayed by HLA class II alleles. The overall objective is to determine the neoantigen profiles predicted to be displayed by HLA molecules in clear cell and non-clear cell RCC variants (unclassified, chromophobe, papillary), and determine whether HED can predict response to ICI based regimens when compared to non-ICI therapy (VEGFR / mTOR).
*Status of Support: Active
Project Number: W81XWH2110942
Name of PD/PI: Kotecha, R
Source of Support: Congressionally Directed Medical Research Programs
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 9/30/2021 - 9/29/2025
*Total Award Amount (including Indirect Costs):
Grant Manager: Joshua McKean joshua.d.mckean3.civ@mail.mil

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY) Person Months (##.##)

2. 2023 3.00 calendar
3. 2024 3.00 calendar
4. 2025 3.00 calendar

OVERLAP:
None