Monitoring of Treatment Related Toxicities from Oral Targeted Agents and Immunotherapy Among Patients with Advanced Renal Cell Carcinoma (RCC) Using Carevive Software, a Single-Arm Phase II Feasibility Study.

Informed Consent Form

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CONSENT FORM

Monitoring of Treatment Related Toxicities from Oral Targeted Agents and Immunotherapy Among Patients with Advanced Renal Cell Carcinoma (RCC) Using Carevive Software, a Single-Arm Phase II Feasibility Study.

Principal Investigator:
Chunkit Fung, M.D., M.S.

This consent form describes a research study, what you may expect if you decide to take part, and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your routine medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you have renal cell carcinoma and are being started on either an oral targeted treatment or infusional immunotherapy.

This study is being conducted by Dr. Chunkit Fung MD, MS, Dr. Supriya Mohile MD, Dr. Rachael Turner MD, PhD, Deepak Sahasrabudhe MD, Adrienne Victor MD and Dr. Bryan Fitzgerald PharmD of the University of Rochester's Department of Medical Oncology.

Purpose of Study

The purpose of this study is to test a computer-based method of at-home symptom reporting and management in patients who are undergoing treatment for renal cell carcinoma. We will keep track of how often you use the software, and the automatically generated self-care plans, and will ask you to rate your experience at the end of the study. Additionally we will keep track of how your symptoms impact your quality of life, distress level, interaction with medical providers and medication adherence. We would also like to collect the reasons eligible study candidates decline participation.

Description of Study Procedures

If you decide to take part in this study, you will be asked to do a number of things listed below.

1. **Screening and initial visit**
   We will first need to confirm that you are eligible for the study. We will also review your medical record to identify information about your cancer, the types of treatments you have received in the past and/or are receiving now. Once we confirm that you are eligible to participate in the study, we have you fill out a survey and demographics form on a tablet device in the office. Your clinician will also ask you about your symptoms and document the results in your medical record. At this visit we will also have you access your first online survey in the office to make sure you do not have any technical issues.

2. **Weekly at-home surveys – Weeks 1-12**
   While the initial survey will be delivered in the office, all subsequent weekly surveys will be taken by you at home for the first 12 weeks. A reminder with a link to the survey will be emailed to you by Carevive Systems,Inc. After you are done with the survey, you will receive self-care management recommendations to help you with your symptoms. Every four weeks the survey will have a few extra questions about how often you interact with your healthcare providers and how often you take/miss your cancer medication. (It is not a requirement that you fill out this survey at home, it can be taken anywhere that you get reliable internet access and feel comfortable answering questions about your health through a secure portal).

3. **Bi-monthly at-home surveys – Weeks 14-48** This will be the same survey you received for the first 12 weeks but will now only need to be filled out every other week. As before, an email reminder and link to the survey will be sent to you. In addition the survey delivered every four weeks will have a few extra questions about how often you interact with your healthcare providers and how often you take/miss your cancer medication.

4. **In-office assessments – Weeks 12, 24, 36 and 48 (approximately)**
   Every 3-4 months at your routine visits, your clinician will ask you questions about your symptoms and document them (using a standardized rating system) in your medical chart. At these visits you will also need to fill out a short survey on a tablet which will ask questions about your quality of life and your level of distress.

5. **End of study assessment – Week 48 (approximately) or when your therapy is discontinued/changed by your clinician**
   Your clinician will again ask you questions about your symptoms, rate them, and document them in your chart. At this visit you will also be asked to fill-out a short survey about your experience with the Carevive Systems in-home surveys and self-care plans.

The following information about your study participation will be included in your electronic health record:

- Documenting you are in this study
- A copy of your signed consent form
- A rating of your reported symptoms as determined by your clinician, according to a standardized scale.

Number of Subjects

Approximately 50 subjects with metastatic renal cell carcinoma will take part in this study.

Duration of the Study

Your participation in the study will last approximately 48 weeks or until your oncologist changes/discontinues your current cancer treatment, whichever is soonest.

Risks of Participation

We expect that this study will involve minimal risk to the subject since it involves a series of surveys and in-office assessments. Potential risks include 1) a breach of confidentiality and 2) the chance that you may find the surveys too time consuming. We have worked to keep all surveys as short as possible to minimize the time burden experienced by subjects. Additionally you would be free to stop the study at any time. There is a risk of loss of confidentiality and privacy because we will collect medical and personal data from you and your medical record. Protected health data and personal data will be kept as confidential as possible but complete confidentiality cannot be guaranteed. To promote subject confidentiality, only research staff at the University of Rochester will know your name and contact information. Otherwise subjects will be identified by a unique identification number. The list that links the subjects name with the identification number will only be accessible to University of Rochester research staff. Additionally, Carevive Systems complies completely with Health Insurance Portability and Accountability Act (HIPAA) privacy standards and they ensure that their

connections are secured and encrypted.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Benefits of Participation
You might not benefit from being in this research study. The potential benefit to you from being in this study might include improved symptom assessment and management of drug-induced side effects.

Alternatives to Participation
You may choose not to take part in this study.

Costs
There will be no cost to you to participate in this study.

Payments
You will not be paid for participating in this study.

Sponsor Support
Carevive Systems, Inc. is providing their technology, in the form of surveys and personalized care plans, to this study. They are not providing financial support.

Circumstances for Dismissal
You may be withdrawn from the study if you do not keep appointments for study visits or if you cannot complete study activities, or if we or your physician feel that continuing in the study would negatively affect your health.

Early Termination
You may withdraw from the study at any time.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will use a unique identification number instead of your name when working with entities outside of the University of Rochester (ie. Carevive Systems).

We will also keep all information you provide to us in locked filing cabinets on a locked floor. Electronic data will be kept by us in a password-protected and secure database and by Carevive Systems on a secure server. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study
- Results of medical tests related to the study

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- Carevive Systems

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Risks of Using Email
The only communication that will occur via email for this study will be survey reminders and links sent from Carevive Systems, Inc. to your chosen email address. You will not be directly emailed by your doctor or the study coordinators as part of this study. You should not use email for communication regarding sensitive medical information. It is important to keep in mind the risks of using email, these include but are not limited to the following:

- Email can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
- Emails can easily be misaddressed.
- Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
- Employers and on-line services have a right to inspect e-mail transmitted through their systems.
- E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
- E-mail can be used to introduce viruses into computer systems.

We recommend that you:

- Avoid use of your employer's computer to access the surveys.
- Inform the researchers of changes to your email address.
- Take precautions to preserve the confidentiality of e-mail.

Risks of using Smart Devices

You may choose to access your email and/or the Carevive Systems surveys and care plans using your smart device instead of a personal computer. Please keep in mind the following risks associated with using your smart device:

- You may be utilizing data (supplied by your cell phone provider) when accessing the surveys and care plans.
- Smart devices may be taken by others and viewed without authorization.
- Smart device content may be viewed by others when it is connected to an unsecure wireless internet source.

We recommend that you:

- Be mindful of available data on your device provider's plan and keep track of data usage.
- Do not leave your smart device unattended and ensure it is password protected.
- Log off of your email and web browser immediately after you are done looking at your surveys and care plans.
- Use a VPN (virtual provider network) when using unsecure wireless internet.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Dr. Chunkit Fung, at (585) 273-5573 or the study coordinator, Park Bogan at (585)-276-4415.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date