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Pilot Study of Multi-platform Assessment of Radiation Toxicity (M-PART) in Head and Neck Cancer Patients Treated with KeraStat® Cream for Acute Radiation Dermatitis

Informed Consent Form to Participate in Research

Ryan T. Hughes, MD, Principal Investigator

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1. SUMMARY

You are invited to participate in a research study. The purpose of this research study is to test how well a mobile device application (called MyCap) will work in assessing skin rashes that are a result of radiation therapy in patients with head and neck cancer. If you decide to participate in this study, you will be required to use your personal mobile device to access the mobile application that is being tested. You are invited to be in this study because you have head and neck cancer and are scheduled to receive radiation therapy. Your participation in this research study will last about twelve weeks (the course of your radiation therapy plus four weeks).

Your participation in this study will involve 1) using KeraStat® topical cream for your radiation rash at least twice a day, or more as needed, while receiving radiation therapy, 2) using a mobile application on your mobile device to answer questions and upload photographs of your rash, 3) weekly visits in conjunction with your radiation therapy visits as well as three additional office visits after your radiation treatment (weekly visits after you finish radiation therapy), and 4) completing a satisfaction survey and participating in an optional phone interview once you have completed all study related activities. There are no known risks associated with KeraStat® topical cream. There is a possibility of some emotional distress associated with completing the surveys and using the mobile application. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include proceeding with routine radiation therapy and skin care according to the advice of your physician, which may include routine moisturizers or other prescription creams. You will not lose any services, benefits, or rights you would normally have if you chose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted].

2. INTRODUCTION

You are invited to be in a research study. Studies help researchers learn new information that may help other people in the future. You are being asked to be in this study because you have head and neck cancer and are scheduled to receive radiation therapy. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask the researchers to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

This study will take place at Atrium Health Wake Forest Baptist Comprehensive Cancer Center.

3. Why Is This Study Being Done?

The purpose of this research study is to test the ability of a mobile device application (MyCap) to collect patient information about their radiation skin rash in patients with head and neck cancer being treated with radiation therapy.

4. How Many People Will Take Part in the Study?

A total of 16 people will take part in this study. Some people may be screened for the study but will not be eligible to participate.

5. How Long Will I Be in the Study?

Your participation in the study is planned to last for about twelve weeks (six to seven weeks of therapy plus 4 weeks after you finish radiation therapy) or until you withdraw, are removed by the treating physician, or if continuation is not in your best interest.

6. What Is Involved in the Study?

If you take part in this study, you will have the following tests and procedures:

Visit	During this visit, you will	How long is this visit?	Reminders
Prior to the start of radiation therapy	• Review and sign this consent form first • Take a pregnancy test (if applicable) • Register in MyCap mobile application and complete proficiency questionnaire with a study team member • Complete demographics and health behaviors form • Complete medical history form • Have vitals taken (height, weight, and BMI) • Complete skin type form • Review current medications • Complete clinician skin rash assessment • Have standardized in-clinic photographs taken • Complete MyCap assessments and upload photographs	1-2 hours	These visits will be coordinated with your radiation therapy visits to minimize trips. Please note if you miss completing your questionnaires in the MyCap app on the day of your visit, a study member will follow-up with you by phone the next day.
Weekly during radiation therapy	• Apply KeraStat® skin cream (as often as needed but at least twice daily, morning and evening) • Complete clinician skin rash assessment • Have standardized in-clinic photographs taken • Complete MyCap assessments and upload photographs	About 30 minutes	These will occur on the same days as your routine, weekly radiation therapy on-treatment visits check-ups. Please note if you miss completing your questionnaires in the MyCap app on the day of your visit,

Visit	During this visit, you will	How long is this visit?	Reminders
			a study member may follow-up with you by phone the next day.
Last weekly visit at the end of radiation therapy	• Apply KeraStat® skin cream (as often as needed but at least twice daily, morning and evening) • Complete clinician skin rash assessment • Have standardized in-clinic photographs taken • Complete MyCap assessments and upload photographs • Complete radiation therapy treatment form	About 30 minutes	This will occur at the last routine, weekly radiation therapy on-treatment visit check-up. Please note if you miss completing your questionnaires in the MyCap app on the day of your visit, a study member may follow-up with you by phone the next day.
Post radiation therapy – weeks 1, 2 and 3	• Apply KeraStat® skin cream (as often as needed but at least twice daily, morning and evening) • Complete clinician skin rash assessment • Have standardized in-clinic photographs taken • Complete MyCap assessments and upload photographs • Receive compensation	About 30 minutes	These are the three visits that will occur outside of normal routine. You will return weekly on the same day as your routine on-treatment check-ups to monitor the skin. At 4 weeks (1 month), these will end. Please note if you miss completing your questionnaires in the MyCap app on the day of your visit, a study member will follow-up with you by phone the next day.
Post radiation therapy week 4	• Apply KeraStat® skin cream (as often as needed but at least twice daily, morning and evening) • Complete clinician skin rash assessment • Have standardized in-clinic photographs taken • Complete MyCap assessments and upload photographs • Complete satisfaction survey	About 1 hour	This is the last study visit, 4 weeks (1 month) from the end of radiation therapy. Please note if you miss completing your questionnaires in the MyCap app on the day of your visit, a study member will follow-up with you by phone the next day.
On or after post radiation therapy week 4 (if selected)	• Complete optional qualitative interview • Receive compensation	About 1 hour	

Optional Interview

If selected, would you be willing to participate in a single, 30-minute phone interview at the end of the study, to discuss your satisfaction with the research study? The interviews will be audio recorded and transcribed for analysis by study team members.

- □ Yes, I agree to participate in the interview
- □ No, I do not agree to participate in the interview

The audio recording and transcription will be considered Protected Health Information if they contain information that identifies you. You understand that you may request the audio recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the audio recording before it is used, but doing so may affect your eligibility to remain in the research study. You should also understand that you will not be able to inspect, review, or approve the audio recording or other media (including articles containing such) before they are used in this study.

We will keep your personal health information as confidential as possible. Your identity will be protected as required by law and according to any policies described in the study consent form. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

7. WILL I RECEIVE THE RESULTS OF THE STUDY?

Due to the nature of the study, and the fact that your cancer care will proceed as it normally would otherwise, research results that are not clinically relevant will not be disclosed to you.

8. WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves minimal to no risk/inconvenience to you. You should discuss the risk of being in this study with the study staff.

Radiation	If you participate in this study, you will be exposed to the same amount of radiation as you would as part of your standard care for treatment of head and neck cancer. Note that being treated with radiation therapy means that you will be exposed to amounts of radiation above what you would normally receive in daily life. To be sure that you do not receive an unhealthy amount of radiation, you should let your doctor know if you have had, or are going to have, any other scans or x-rays as part of your medical or dental care. It is important that you let your study doctor know if you already are participating in, or plan to participate in, any other research study that

	involves radiation exposure.
KeraStat® skin cream	There are no known adverse effects of KeraStat Cream. Per the cream's package insert , it should not be used on bleeding wounds and should be used with caution on infected wounds. A healthcare provider should be contacted if there are signs of infection, change in wound color or smell, wound doesn't show signs of healing or if any other unexpected symptoms occur.
Minimal Risk	The risk of harm or discomfort that may happen because of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.
Confidentiality and privacy	Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. The MyCap application, used for completing questionnaires in this study, is owned by a third-party. The privacy and security for the data provided using the app is the responsibility of the application owner.
Interview questions and assessments related to your radiation therapy or other information that may require reporting to authorities outside of the study	As part of this study, you will be asked questions about your radiation therapy, your health, how well you were able to manage the mobile application, and questions about your satisfaction with the mobile application. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

9. Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. As a part of this study, you will receive a new skin cream (KeraStat® cream) that we think helps to relieve radiation skin burns at no cost to you. We are currently working to better understand if this cream helps patients more than current skin care options and over the counter moisturizers. You may benefit from the study if the KeraStat® cream helps to relieve skin burns you may experience due to your standard of care radiation treatment. We hope the results of this study will benefit other people in the future.

10. What Other Choices Are There?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Some other choices may include proceeding with routine radiation therapy and skin care according to the advice of your physician, which may include routine moisturizers or other prescription creams.

11. What Are the Costs?

Study costs, including the KeraStat® topical skin cream, the mobile application and any other procedures that would only be done as part of the study will be paid for by the study sponsor.
If you decide to participate in this study, you will be required to use your personal mobile device to access the mobile application that is being tested. Costs for your mobile device and data used and your regular medical care not related to this study, including your scheduled radiation therapy and office visits, will be your own responsibility.

KeraStat® cream produced by KeraNetics LLC. Wake Forest University Health Sciences (WFUHS) has an ownership interest in Keranetics, and therefore WFUHS could financially benefit from the study results if KeraStat is marketed for use related to this research.

12. Will You Be Paid for Participating?

You will be paid up to $250 in gift cards for participation in this study: a $50 gift card for each of three weekly study-related visits between completing radiation therapy and your routine 1-month follow-up visit, and a $100 gift card for your participation in the optional interview (the option to participate in the interview, if selected, is located on page 5 of this informed consent form). If you withdraw from the study before completion for any reason, you will be paid for the study-related visits or interviews you complete.

13. Will Your Research Records be Confidential?

Your participation in this research and any study records created about your participation will be kept as confidential as possible. The overall results of this study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be shared unless you give your permission or is required by law to protect you or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

14. What If I Am Harmed from Being in The Study?

This study is a low-risk intervention, and it is extraordinarily unlikely that you are harmed because of your participation; however, if you get hurt or sick from being in this study, you should seek medical care. Be sure to tell the researcher as soon as possible. You may receive care at Advocate Health. There is no plan to pay for lost income or any non-medical costs that might result from the illness or injury. Advocate Health - Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for treatment of injuries or illnesses. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

15. Who will see my Protected Health Information?

Who may have access to my information:	***Purpose:***
Any sponsor, including future sponsors, of the study and anyone working on behalf of a sponsor or future sponsor	To oversee the study and make sure the information is correct.
Consultants and employees of Advocate Health – Wake Forest University School of Medicine, including IRB members.	To protect the rights and safety of subjects and make sure the study information is correct.
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries).	To make sure applicable laws are being followed.
Organizations that grant accreditation to hospitals and research programs.	For Advocate Aurora Health to remain accredited.
Monitors, auditors, IRB or other regulatory agencies may be granted direct access to your medical record.	To verify clinical trial procedures or data.

By signing this form, you are giving the researchers permission to use and share your personally identifiable health information. This includes direct access to your medical records.

Please note that the study doctor or study staff may also share personal information about you if required by law (for example, if the study doctor or study staff suspects that you are going to harm someone or yourself, reporting of communicable disease (HIV, hepatitis, tuberculosis, etc.). If you have questions about this, please ask the study doctor.

How will my information be used for this study?

You must authorize the use and sharing of your information by signing this form or you cannot be in the study.

The study principal investigator and study staff will collect, use, and share identifiable health information about you for the following reasons:

- to conduct this research study.
- to review the study, and to check the safety and results of the study.
- to seek government approval of an investigational study drug, vaccine, device or product if such was involved in the trial.
- to assist a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Information used and shared may include:

- information from your medical records related to the research or your routine medical care.
- information collected about you during the research and any follow-up related to study visits, tests, procedures, outcomes, etc.

The collected information may contain your name, address, telephone number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

How will my information be kept confidential?

We will keep your personal health information as confidential as possible. Your identity will be protected as required by law and according to any policies described in the study consent form. Researchers may share your information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually, the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Once your information leaves the organization, we cannot control how it is used, and the law may not require other groups to protect the privacy of your information.

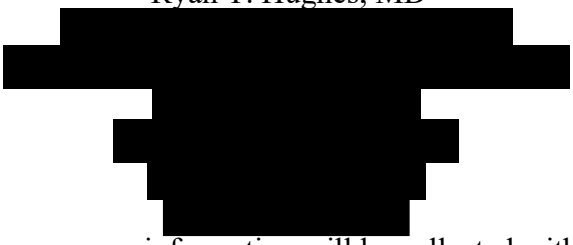
To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally will have access to your health information.

If this study is designed so that you are intentionally not told what treatment or study intervention you are receiving (called a blinded study), you will not have access to health information in your medical record that was collected as part of this study until those who run the study determine it is no longer necessary to keep you blinded. This usually occurs after everyone in the study has completed study treatment or intervention but can sometimes last until all study data is collected and analyzed.

How do I cancel my authorization?

You can cancel your authorization to use and share your information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and remain in the main study.

Ryan T. Hughes, MD



If you cancel your authorization, no new information will be collected without your permission. The study doctor and study staff will still be able to use and share your information that has already been collected to maintain the integrity of the study.

When will my authorization expire?

This authorization to use and share your information expires at the end of the research study when data analysis is complete, and study records have been destroyed.

If study information is used for scientific publications or educational purposes, all identifying information will be removed.

16. What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

You may be asked to complete a survey about your experiences participating in a research study.

17. Whom do I call if I have questions or problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Ryan T. Hughes at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss

problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact [redacted].

It is your choice if you would like your personal doctor to be informed of your participation in this study. Please check one of the boxes below to show your choice (must be checked by the subject):

□	I agree to have my personal doctor informed of my participation in this study by the study team
□	I do not agree to have my personal doctor informed of my participation in this study by the study team

The study doctor will collect the name of a person who may be contacted if you cannot be reached. He/she may be asked how to contact you and about your health status. Please tell the study doctor about any change to his/her contact details. Remember to tell the person you identified as the contact that he/she may be contacted by the study doctor. If your designated contact is not reachable, the study doctor may use other ways to locate you or your contact person (such as public records).

18. USE OF PERSONAL MOBILE DEVICE

To participate in this study, you will be asked to use your mobile device to complete surveys and upload photos of your skin using the MyCap application. Please provide your initials below to confirm that you will be able to use your mobile device.

Yes, I am willing to use my mobile device _____
Initials

19. Signatures

Subject name: _____

- I have read this form and the research study has been explained to me.
- I have had ample time to consider participation in the study and have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I understand the research study and voluntarily agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.
- I agree to follow the investigator's instructions.
- I understand and agree that representatives from the sponsor, regulatory authorities and the institutional review board will be granted direct access to my medical records.
- I understand that I may decide to refuse participation or stop participating at any time without penalty and without affecting the quality of my health care or the relationship with the study doctor.
- I understand that there may be consequences to my withdrawal from the study as noted within this document.
- I understand and agree that personal information about me will be collected in this study and from my medical records and used and processed (manually and by computer) for the purposes of the

study by the manufacturer of a medical device used in my treatment or any other designated party that is involved in the study (e.g. hospital, study doctor, regulatory authorities, ethics committees).
- If I so choose, I have provided the name of a person to be contacted by the principal investigator in case I cannot be reached for follow-up.

Participant signature Date Time

Legally Authorized Representative signature (if applicable) Date Time

Relationship to Participant: □ Court Appointed Guardian □ Heath Care Agent

ÿ Other appropriate LAR as determined by state law or system policy.

For Site Use only:

My signature below certifies the following:
- The subject has been given enough time and an adequate place to read and review this form.
- All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began.
- The subject has had a chance to ask questions and receive answers about this study.
- The subject expressed understanding of the study.
- The subject/LAR will receive a copy of the signed and dated consent form/authorization.

Name of person obtaining informed consent (print)

Signature of person obtaining informed consent Date Time