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Wake Forest®
School of Medicine

Department of *Radiation Oncology*

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

Study Staff Information Sheet
Ryan T. Hughes, MD, Principal Investigator

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 (MyCap) will work in assessing skin rashes that are a result of radiation therapy in patients with head and neck cancer. You are invited to be in this study because you are a member of the clinical protocol data management (CPDM) research staff assisting participants with study activities, specifically with the MyCap application. Your participation in this research will involve participation in an interview about your experience and satisfaction with the research study and will last about 30 minutes.

Participation in this study will involve an interview about your experience and satisfaction with the implementation of the MyCap application from a research staff perspective. All research studies involve some risks. There is a possibility of some emotional distress associated with completing the interview about your experience and satisfaction with the research study. You 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.

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. The person in charge of this study is Ryan T. Hughes, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: Ryan T. Hughes, MD, [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] or the Research Subject Advocate at Wake Forest at [redacted].

How Many People Will Take Part in the Study?
Up to 4 research staff members and 16 patients will take part in this study.

What Are the Risks of the Study?
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.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. 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.

As part of this study, you will be asked questions about your experiences and satisfaction with the research study and its implementation. 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.

Are There Benefits to Taking Part in the Study?
You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

What Are the Costs?
All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Will Your Research Records be Confidential?
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant 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 if this study falls within its jurisdiction.

Will You Be Paid for Participating?
You will be paid a $100 gift card if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will not be compensated.

What About My Health Information?
In this research study, any new information we collect from you about your health, or behaviors is considered Protected Health Information. The information we will collect for this research study includes: your feedback about helping patient participants use the MyCap.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed, or it will be de-identified You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Ryan T. Hughes that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Ryan T. Hughes, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

You may choose not to take part, or you may leave the study at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. This could be because the interviews are no longer needed or the entire study has been stopped. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.