

Improving Outcomes for Older Adults Undergoing Radiation Therapy: Prospective Cohort Study

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NCT05721053

Document Date: 2/27/2025

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

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Study ID: STUDY-21-00960
Form Version Date: 1DEC2023

STUDY INFORMATION:

Study Title: Improving Outcomes for Older Adults Undergoing Radiation Treatment – Prospective Cohort Study

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, Mount Sinai Beth Israel, Mount Sinai West

Lead Researcher (Principal Investigator): Kavita Dharmarajan, MD, MSc

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Phone: (646) 605-5841

SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to improve care for people ≥ 55 years of age who are receiving radiation therapy (RT). The goal is to gain a better understanding of your daily functioning, quality of life, and prevalence of symptoms throughout your course of radiation and follow up. The findings of this study will help radiation oncologists make more informed decisions with patients ≥ 55 years of age.

If you choose to take part, you will complete research surveys and assessments during your regularly scheduled visits and are giving the research team permission to access your medical record. Participating in this study does not require extra trips to the hospital. The surveys ask about activities of your daily life and the assessments include standing, walking, and cognitive tests. There are five total time points: before you start radiation, the end of your radiation, and at the 1, 3, and 6 month follow up appointments. Completing the surveys usually takes an additional 15-30 minutes. You will be compensated \$10 for each visit completed.

If you choose to take part, the main risks to you are risk of loss of private information, but there are procedures in place to minimize this risk.

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Rev 11.11.2022 (Amendment 1-03.09.2023)



Effective Date: 2/27/2025
End Date: 2/26/2026

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You will not benefit directly from taking part in this research.

If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you are receiving radiation treatment for cancer.

Your participation in this research study is expected to last throughout your radiation treatment and in follow up, until 6 months post radiation.

There are 225 people expected to take part in this research study at Mount Sinai Health System's Department of Radiation Oncology (Mount Sinai Hospital, Mount Sinai Union Square, Mount Sinai Chelsea and Mount Sinai West).

Funds for conducting this research study are provided by the National Institutes of health (NIH) and the national institute on Aging (NIA).

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. 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 website at any time.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

We will ask you to complete surveys and assessments at five time points: before you start radiation, the end of your radiation, and at the 1, 3, and 6 month follow up appointments. These occur at your regularly scheduled visits. We will ask you about the following:

- How you are **feeling physically**, including walking, bathing, lifting, and going up/down stairs. It will ask if you have other conditions that may interfere with these activities of daily living.
- How you are **feeling emotionally**, including frequency and severity of feelings of anxiety, depression, calm, loved, supported, etc. These will include questions about your level of spirituality, social support, and social activities.
- Complete **physical assessments**. For example, we will time your standing and walking speeds.
- Complete **cognitive assessments**. For example, we will assess your memory and recall ability.

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This study involves no extra bloodwork, procedures, or visits. By consenting for this study, you are giving us permission to keep track of your treatment and your treatment response. You are also giving us permission to track your radiation treatment and pertinent personal information, such as date of birth, demographics, height, and weight.

USE OF YOUR DATA:

In addition to being used to complete this research study, your personal information (such as, name, address, date of birth), and study data may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed and it will be replaced with a code.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

- Spending 15-30 minutes before/after your regularly scheduled visit to complete surveys and assessments.
- Promptly reporting any side effects you experience regarding your radiation treatment to your radiation oncologist.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will be paid \$10 each time you completed a particular time point survey. There are five total time points, for a total of \$50. Being in this study will not cost you anything extra.

POSSIBLE BENEFITS:

This study is not designed to benefit you personally. However, possible future benefits to others include improved treatments for future cancer patients treated with radiation therapy.

POSSIBLE RISKS AND DISCOMFORTS:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- Group Risks - Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or discrimination.

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- Loss of balance – If you feel like you might lose balance during the physical assessments, we will stop. Your safety is our top priority.
- If there are any assessments that make you feel uncomfortable, they can be skipped.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. At that point, your information will be removed from our database and no new information will be collected.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data withdrawn or labeled so that they will not to be used in additional projects or shared. If your data have already been shared with researchers, those researchers will be asked to stop using them. However, if any data have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data that have already been used will not be affected by your decision. If your data have already been deposited in an external repository, the study team will request that your data be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research

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study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at (646) 605-5841.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at <http://icahn.mssm.edu/> where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?

PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this study, the research team at the hospital(s) involved in the research will collect your name, address, telephone/fax numbers, dates directly related to the individual (birth, admission, discharge, date of death, etc.), medical records number, health plan numbers, photographic images.

The researchers will also get information from your Mount Sinai electronic medical record.

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Why is your PHI being used?

Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, payment amount, and related information for tax reporting purposes.
- *If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?

As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).

In almost all disclosures outside of Mount Sinai, you will not be identified by name, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving

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the institution will be stripped of direct identifiers. Additionally, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?

Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?

You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The research team is not required to release research information to you that is not part of your medical record

Do you need to give the researchers permission to obtain, use or share your PHI?

NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

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Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your personal information, study data and/or samples with anyone who is not a member of the research team, including any family members or friends, other than those identified above. However, you should know that if it is learned that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the research team may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

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ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant

Printed Name of Participant

Date

Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate

Printed Name of Consent Delegate

Date

Time

WITNESS SECTION:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of Witness

Printed Name of Witness

Date

Time

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