Memorial Sloan Kettering Cancer Center
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Participant Informed Consent for Clinical Research

Study title for participants: Automated Geriatric Co-Management Program in Older Patients with Solid Mass or Nodule Suspicious for Cancer

Official study title for internet search on http://www.ClinicalTrials.gov: Feasibility and Effectiveness of Automated Geriatric Co-Management Program on Improving the Perioperative Care of Older Patients with Solid Mass or Nodule Suspicious for Cancer

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If you are the parent or legal guardian of the person who is being asked to participate in this research study, you may give consent on his or her behalf. The word "you" in this document refers to your child, if the participant is a minor, or to a person with a cognitive impairment for whom you are the Legally Authorized Representative (LAR).

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

You are being asked to take part in this study because you are at least 65 years old, have a solid mass or nodule, and are being considered for surgery.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered. See the *Where can I get more information?* section of this document for more information about research studies and for general information about cancer.

Why is this study being done?

This study is being done to answer the following question:

Is the automated geriatric co-management program possible and effective in improving the care of older patients before, during, and after surgery?

What is the usual approach to my solid mass or nodule?

Surgery for solid mass or nodule in older adults can cause side effects such as infection or slow recovery. People who are having surgery and not in a research study will usually be monitored and managed by the Surgery team. The Surgery team may refer patients to the Geriatric team (primary care

doctors who specialize in the care of people over 65 years old) for consultation for any age-related impairments.

What are my other choices if I decide not to take part in this study?

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will either see the surgical team or a geriatrician for your care during and/or after surgery. You will receive surgery for your solid mass or nodule through routine care and according to your surgical team's recommendation. The study doctor or a member of the study team will follow your condition for 30 days after surgery. During this time, the study doctor or a member of the study team will collect information about your health, test results and treatment plan.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

There are minimal risks to you for being in this study. You may experience some discomfort during the 4-meter walk test, where you will walk in your usual pace for 4 meters (about 13 feet). The risks from your routine care are not risks of this study. More information can be found in the "What risks can I expect from taking part in this study?" section.

Benefits

Participating in this study will not improve your health, but it may provide the Surgery team with more information about your condition in a timely manner, which may help you to receive better care before, during, or after surgery. Researchers hope that information from this study will help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop participating in the study at any time.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide to stop, let the study doctor know as soon as possible.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest

- You do not follow the study rules
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor, Memorial Sloan Kettering Cancer Center (MSK). The study sponsor is the organization that oversees the study

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

You have a solid mass or nodule and are being considered for surgery to remove the mass/nodule. The purpose of this study is to find out if it is possible to use the automated geriatric co-management program to manage your care before, during and after surgery.

Previous studies have shown that the outcome of older patients after surgery tends to improve if they see geriatricians before and after surgery. The automatic geriatric co-management program is designed to provide the Surgery team with recommendations for managing your age-related impairments automatically. This new method of managing your care may be more timely and efficient than the usual approach because you will not have to wait to see geriatricians in person. Researchers would like to know if the automated co-management program can provide recommendations that can be followed by the surgical team, and whether this program can improve your post-surgery outcome as if you were seen by a geriatrician.

About 200 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

What are the study groups?

This study has two study groups:

- Participants in Group 1 will be in the automated geriatric co-management program.
  - Following your surgery, and while you are in the hospital, you will be managed by the Surgery team.
  - Your Surgery team will receive a list of geriatric recommendations for your age-related impairment(s). The automatically generated list will provide the Surgery team with guidance on services you may need before and after surgery, such as physical therapy or exercises. Your primary doctor or another doctor involved in your treatment plan will assess your condition and determine whether you are ready for surgery.
- Participants in Group 2 will be in the in-person geriatric co-management program.
  - You will be referred to the Geriatric service where a geriatrician will clear you for surgery.
  - The Geriatric service will conduct routine tests and assessments and make final recommendations to the Surgery team. After surgery, the Geriatric service will assist the Surgery team in your care.

A computer will assign you by chance, like flipping a coin, to a study group. This process is called randomization, and it is done by chance because no one knows if one study group is better or worse than the other. Your doctor will tell you what group you are assigned to.

What extra tests and procedures will I have if I take part in this study?

Before you begin the study:

The study doctor will review your medical records and the results of your exams, tests, and procedures to see if it is safe for you to take part in this study. During your baseline or pre-operative visit you will be screened for study eligibility. If you are eligible and consent to the study, your sociodemographic characteristics will be collected, and you will complete the electronic Rapid Fitness Assessment (eRFA) and the 4-Meter Walk test. The eRFA questionnaire is part of your usual care and will determine your body's overall condition and whether you have any age-related impairments.

During the study:

Participants in both study groups will receive the same assessments. The study doctor or a member of the study team will ask you about any age-related impairments that you may have.

You will continue to receive your usual care before and after your surgery, including the 4-meter walking test, where the amount of time needed to walk 4 meters (13 feet) at your usual pace will be measured. You will also complete an electronic Rapid Fitness Assessment (eRFA), before and after your surgery. You will see the Surgery team within about 2 weeks after your surgery, where you will undergo routine tests to see if you have any side effects from the surgery.

If you are in Group 1, your surgical team will receive a list of recommendations to manage your care. If your surgeon thinks you have age-related impairments that might be better managed by geriatricians, then you may be switched over to Group 2, where you may see a geriatrician for managing your care.

The study doctor or a member of the study team will continue to collect information about your health, test results, and post-surgery outcome for up to 30 days after your surgery.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or at home, and you may spend more time than usual in the hospital or doctor's office for assessment of surgery-related risks
- You may feel distressed or uncomfortable when walking around for 6 minutes

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments.

Is there a conflict of interest for this study?

This study is sponsored by Memorial Sloan Kettering Cancer Center. No conflicts of interest have been identified for either the institution or the investigator(s) in this study.

What are the costs of taking part in this study?

There is no cost for you to take part in this study. You and/or your health plan/insurance company will have to pay for all the other costs of caring for your disease while you are in this study, including the costs of insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

Ask the study doctor or nurse for help finding the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

We will offer you treatment for research injuries that happen as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance company.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

The NIH has given this research study a Certificate of Confidentiality. This Certificate does not indicate that the NIH or the US Government recommends that you take part in this study. The Certificate helps us keep your health information private. Your records for this study include information that may identify you. The Certificate of Confidentiality lets us refuse demands to release your study records. The

Certificate can be used in any federal, state, or local legal matter. The cases in which we cannot use the Certificate are explained below:

- To refuse a demand from the US Government for review of study records in the event of an audit of the research study
- To refuse a request for your study records if you or your legally authorized representative have given written permission for their release

In the future, your information (data) and biospecimens (blood, tissue, saliva, etc.) may be de-identified, which means that your data and/or biospecimens will be assigned a unique code, and the list that links the code to your name will be stored separately from your biospecimens and data. Your de-identified information and biospecimens may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

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

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

Research Authorization for the Use and Disclosure of Protected Health Information (PHI)

Automated Geriatric Co-Management Program in Older Patients with Lung Mass

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator(s): Armin Shahrokni, MD, MPH, and Robert Downey, MD.
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study approach
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the intervention being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your

ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to your medical record at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your 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 212-306-7500. These agencies are responsible for protecting your rights.

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent
I have fully explained this clinical research study to the participant or to his/her Legally Authorized Representative (LAR). In my judgment, and in that of the participant or his/her LAR, sufficient information, including risks and benefits, was provided for the participant or his/her LAR to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's (or Legally Authorized Representative's [LAR's)]) statement
I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my/the participant's protected health information (data about myself/the participant); and (3) to state that I have received a signed and dated copy of this consent form.

Participant/LAR must personally sign and date		
Participant/LAR signature		**Date:**
Participant/LAR name (Print)		
LAR relationship to participant		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's (or LAR's) language, and I confirm that the consent discussion was appropriately interpreted for the participant (or LAR).
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____
(The name of the witness must be documented in the EMR.)

Interpreter (if required)
Name of interpreter (if present): _____
ID number (if phone interpreter): _____
(The interpreter's name or ID number must be documented in the EMR.)

The participant/Legally Authorized Representative must be provided with a **signed copy** of this form.