ROSWELL PARK CANCER INSTITUTE

Title: Does increased mobility assessed with 3D motion tracking technology lead to early post-operative recovery among patients undergoing oncologic surgeries?

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Roswell Park Study Number: I 80918

Consent Form Given to Participant Taking Part in a Research Study

KEY INFORMATION ABOUT THIS RESEARCH STUDY

This is a research study being done by doctors at Roswell Park Comprehensive Cancer Center. Research studies include only those people who choose to take part. Your participation is voluntary. Please take your time to make your decision. Discuss it with your family and with people who are important to you.

We are asking you to take part in this study because you are a post-operative inpatient.

Study Purpose: The purpose of this study is to identify the minimum required level of mobility after inpatient oncologic surgeries to enhance early post-operative recovery and decrease early post-operative complications. This will be assessed objectively using 3D motion tracking technology (XSENS).

Study Costs:
There are no costs to you associated with this study.

Study Duration and Number of Participants: It is expected this study will take about 2 years or will continue until the needed number of participants are enrolled. This study will include about 80 patients from Roswell Park.

Your participation in this study will last for 30 days after any inpatient oncologic surgery.

Research Tests and Procedures: If you take part in this study you will have your movement tracked using a 3D motion tracking system (XSENS).
Section 1 of this document provides additional information on the tests and procedures involved with this study.

Risks: While you take part in this study, you may be at risk for fall associated with mobility after surgery. The risk of fall is seen in 1.6 cases per 10,000 patients). You should discuss these risks with your doctor/study investigator.

It is very important that you notify your doctor/study investigator right away about any problems, or unusual experiences you may have while on this study. This will decrease the chance that the problems continue or become worse.

Sometimes there are other resources that we can provide to you to make you more comfortable. If severe side effects do develop, you and your doctor/study investigator may decide it is in your best interest to stop taking part in the study.

Potential Benefits: You understand there is no guarantee that being on the study will help you. Future patients / participants may be helped from the results and information gained from this study.

Other Options: It is your decision to join. There are no penalties for not taking part in this study.

The type of study, the risks, benefits, discomforts, and other important information about this study are discussed below.

DETAILED INFORMATION ABOUT THIS RESEARCH STUDY

It is important that you read and understand the following facts that apply to anyone that takes part in our studies:

a) This study is considered research. It is investigational.
b) Taking part in the study is voluntary.
c) You may withdraw from the study at any time without penalty, loss of any benefits or access to care at Roswell Park to which you are otherwise entitled.
d) Personal benefit may not result from taking part in the study, but knowledge may be gained that will benefit others.
e) If you should decide not to take part in this study, it will not affect your care at Roswell Park now or in the future.
f) If we become aware of important new findings that relate to your participation or continued participation in this study we will discuss them with you.
g) If you decide to stop being in the study, you should talk with your doctor first about this decision so you are informed about stopping study participation safely.

1. What is the purpose of this study?

The purpose of this study is to identify the minimum required level of mobility after inpatient oncologic surgeries to enhance early post-operative recovery and decrease early post-operative complications. This will be assessed objectively using 3D motion tracking technology (XSENS).

2. What are the study groups?

There are two groups in this study, the control and intervention groups. Each participant will be assigned randomly to one group based on a computer generated number. In the control group participant's movement will be tracked with the 3D motion tracking system on a daily basis. This will take place inside the hospital after any inpatient oncologic surgery until the day of discharge to home. This group will be instructed to move for 2 laps in the ward. The requirements for the intervention group participants will be the same as for the control group except they will be instructed to move out of bed for 30-45 minutes daily until their discharge to home. Both group's participants will be followed for 30 days after the procedure to note any complications or readmissions.

3. If I take part in this study, what tests and procedures will I have done?

Prior to surgery, you will be given a Godin Leisure-Time Exercise Questionnaire to assess your typical leisure time physical activity. After surgery, in the hospital, you will wear a 3D tracking sensor whenever you move out of the bed. The sensor is used to monitor the participants mobility time and range of movement, from the first day after surgery until you are discharged from the hospital. XSENS is a wireless technology that makes use of sensors. The sensors are applied in a non-invasive manner. There are various configurations of the sensors that can be utilized. The minimum number of sensors needed is 7. They are applied by using Velcro bands. The entire set-up takes about 5-10 minutes.

Information will also be collected from your medical record regarding the gastrointestinal symptoms such as nausea, vomiting, passing flatus or stool and any degree of abdominal pain. Chest symptoms including coughing, sputum production, chest pain and fever will be retrieved from your medical record.

You will complete a post experiment questionnaire about your experiences and quality of life post discharge. This will be done either over the phone or during one of your standard follow ups.

4. Will I be informed of research results?

If we learn new information that may be important to your health or to your disease condition, we will share that information with you.

Overall findings from this study (including those from other participants) that may be important to your health or about your disease or condition will be provided to you.

5. Why would I be taken off the study early?

You may be taken off the study for any of the following reasons:

- You do not follow the study schedule or requirements
- New information becomes known to us that would influence your decision to remain on the study
- Any changes in your post-operative course
- You no longer want to participate

- The study doctor may decide to stop or change the study.
- If patients cannot complete the walking tasks they will be excluded and replaced

6. What risks and discomforts are involved?

While you take part in this study, you may be at risk of fall. Falls can have a variety of outcomes ranging from no injury or minor injury, to serious injury such as bruises, skin contusion, bone fracture or intracranial bleeding. Falls that not result in physical injury can lead to self-imposed limitation of activity and might decrease your functional ability.

7. What will this cost?

Examinations, scans, laboratory tests, and other medical procedures and treatments that would routinely be needed to monitor and treat your illness are known as "standard of care" services. Charges for these services will be billed to you and/or your insurance carrier in the usual manner. You will be responsible for all co-payments, deductibles, and/or account balances as determined by your individual health insurance contract.

Examinations, scans, laboratory tests and other medical procedures and treatment that are required only for the clinical research study and are not needed for the usual care of a patient with your disease are known as "research related" services. Research related services will not be charged to you or your insurance.

The following procedure that you will receive as part of your clinical research study is considered research related: XSENS motion tracking.
This procedure will be provided to you at no cost.

There are many different types of insurance plans and contracts. It is not possible to tell you in advance the exact amount your insurance will pay and what your financial responsibility will be. If you wish, a financial counselor can meet with you to help answer your questions regarding insurance coverage issues before you decide to participate in this study. A Financial Counselor can be reached at 716-845-3161.

There are certain insurance plans that will not cover charges for any care related to an experimental or investigational therapy or study. These plans may deny coverage for even the routine, standard of care medical services you will need to receive during the time you are enrolled in the study. If you have an insurance plan that does not cover participation in a clinical research study, or if you currently have no insurance coverage, a financial counselor can meet with you to provide an estimate of the costs that would be associated with participation in this study. A payment schedule can be developed if needed. A Financial Counselor can be reached at 716-845-3161.

A representative from the Patient Access Department can help you obtain authorizations from your insurance carrier when needed. A representative from the Patient Access Department can be reached at 716-845-1049.

You and /or your insurance company will be responsible for charges related to the administration of drugs used in this clinical research study and for charges for medications that may be needed to prevent or control side effects.

If you develop complications or side effects from your participation in this clinical research study, medical treatment will be provided at the usual charge. A financial counselor can be reached at 716-845-3161 to provide an explanation of coverage and to answer questions you may have regarding study related billing.

8. What are my responsibilities in this study?

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

- Keep your study appointments.
- Tell your doctor about:
  - any side effects
  - if you have been or are currently in another research study.

9. What happens if I am injured as a result of this study?

If you believe you have been injured as a direct result of your participation in this research study, notify the Roswell Park Patient Advocate at (716) 845-1365 or the Study Doctor at (716) 845-4107.

Medical diagnosis and treatment for the injury will be offered, and a determination will be made regarding appropriate billing for the diagnosis and treatment of the injury. A financial counselor can be reached at 716-845-3161 to provide an explanation of coverage and to answer questions you may have regarding study related billing.

You do not give up any legal rights by signing this form. You are not prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

10. Will I be paid for joining this study?

You will receive no payment for taking part in this study.
It is possible that this research project may result in developing treatments, devices, new drugs, or procedures that could be used for commercial profit by the sponsor or other entities. If this happens, you understand that you will not receive any financial payment or share in any commercial profit for the use of your information and biospecimens (such as blood or tissue samples) collected as part of this research.

11. Where can I find more information?

You may call the NCI's Cancer Information Service 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 information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

For accurate cancer information including Physician Data Query (PDQ), visit http://cancernet.nci.nih.gov.

12. Who do I contact with questions?

You are free to ask questions at any time about this study and to ask for more information from the doctor identified on this consent. If you have any questions, concerns or complaints about this study, you should contact Dr. Khurshid Guru at (716) 845-4155 at Roswell Park Cancer Institute. In case of an emergency after regular hospital hours, you should telephone (716) 845-2300 and ask for the medical doctor on call.

If you have questions about your rights as a research subject or you feel you have been injured as a result of your participation in this research study, you can call the Roswell Park Cancer Institute Patient Advocate (Support) Office at (716) 845-1365. You should also feel free to contact the Patient Advocate Office at any time while considering participation, during participation or once your participation is complete. This office is unaffiliated with any specific research study. They can help you obtain additional information regarding your research participation and your rights as a research subject or how to proceed should you feel you have been injured as a result of your participation. They are available to discuss any problems, concerns, questions or input you may have.

It may be necessary to contact you at a future date regarding new information about this research study. For this reason, we ask that you notify the Patient Access office at 716-845-1049 or stop at the Registration Desk in the Lobby of Roswell Park to update us of any change in your address.

CONFIDENTIALITY AND USE OF HEALTH INFORMATION

If you volunteer to take part in this research study, and you sign this document, you give permission to the study doctor and research staff to use or disclose (release) your health information that identifies you and is collected as part of the research study described in this consent. This means that others may know or be able to find out your identity, use your health information and share it with others. We want you to know who may use this information and how they may use it. We also want to tell you about your rights before you agree to take part in the study.

If you volunteer to take part in this research study, you consent to the release of your health information from other medical facilities for any moderate to life-threatening or fatal adverse events that occur while on study treatment through 90 days after treatment ends.

Who may see this information?

- Dr. Khurshid Guru and all the members of the study/research team and other health care professionals at Roswell Park

- Government or Regulating Agencies such as the FDA, DHHS, NCI, NIH or other agencies worldwide
- Government agencies that must receive reports about certain diseases and conditions
- Institutional Review Boards or Data Safety and Monitoring Boards at Roswell Park and its affiliates or outside of Roswell Park.

What information may be collected, used and shared?

Health information that identifies you and relates to your participation in this study will be collected and created. This may include the following:

- Health information, sometimes known as "Protected Health Information" (PHI) can include your name; address, patient identification number; medical record number; date of birth; photographs; information about your health, including past medical history, treatment, diagnosis, test results and any other information about your health or medical condition; or about payment of charges for medical treatment found in your medical record or other records maintained by Roswell Park.

- Information from the procedures used to find out whether you are eligible to take part in this study. This may include physical examinations, blood and urine tests, x-rays and other procedures or tests, and any other information that you may release to us, including information about your health history.

- Information obtained in the course of the study including information about your response to any treatments you receive, information related to study visits and phone calls, physical examinations, blood and urine tests, genomic or genetic tests, x-rays and other procedures or tests, and any other information about your participation in this study.

Why will this information be used and/or shared?

PHI and other information that may identify you will be used and given out to others to carry out the research study. The sponsor will analyze (test) and evaluate the results of the study. The sponsor, its agents, assigns, government agencies, and others may visit the research site to follow how the study is being done and may review your information for this purpose.

This information may be given to the FDA. It may also be shared with other governmental agencies in this country and in other countries. This is done for participant protection and so the sponsor can receive marketing approval for any new products that may result from this research. The information may also be used to meet the reporting needs of the governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed (shared).

Your health information may also be stored in a research database or repository. This information may then be used for other research, either de-identified or identified, with or without further IRB review and approval. This information will be kept indefinitely.

What if I decide not to give permission to use and give out my health information?
If you refuse to authorize the collection, use and disclosure of your health information as indicated above, you will not be able to be in this research study.

Your decision not to sign this authorization or to withdraw from the study will not involve any penalty or loss of benefits to which you are otherwise entitled and will not affect your access to non-research related health care here.

What happens if I want to withdraw my authorization?
You may change your mind and revoke (take back) this authorization at any time, except to the extent that Roswell Park has already acted (used or disclosed health information) based on this authorization. To revoke/withdraw this authorization, you must write to the study doctor (name and address is on the first page of this form) and let the doctor know that you are withdrawing your authorization to use and disclose your information.

If you should die while enrolled in or after taking part in this study, your health information may be used or disclosed solely for research purposes without getting any added authorization.

The results of clinical tests or therapy performed as part of the research may be included in your medical record and will not be removed from the record if you withdraw.

If all information that does or can identify you is removed from your health information or biospecimens (such as blood or tissue samples), the remaining information or biospecimens will no longer be subject to this authorization and may be used or disclosed for other purposes, including use for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

May I review or copy the information obtained from me or created about me?
To keep the integrity (truthfulness) of this research study, you will not have the right to review or copy your health information related to this research until the study is complete. At the end of this research study and at your written request, you may have access to your health information. This information is kept in a designated record set, which is a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Roswell Park to decide about care and treatment. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by Roswell Park.

If it is necessary for your care and/or treatment, your health information will be provided to you or your referring or primary care doctor.

When does this authorization end?
This authorization does not have an end date.

What happens to my health information after it is given to others?
If you sign this form, the health information collected from you and shared as indicated above, may be re-disclosed to third parties who are not subject to the same laws as those in the United States and may no longer be protected. There is a risk that your information will be given to

others without your permission; however, the Sponsor also has protections in place to assure the security of your health information.

Authorization

As a participant in this study, you agree to allow the use of your health information for research purposes. You understand that your health information will be used/disclosed by Roswell Park as indicated in this document. You understand that you have a right to withdraw your authorization for use of your health information in writing, but the information which has already been used or disclosed before your written withdrawal will continue to be used for research purposes. Finally, you understand your health information that has been disclosed by Roswell Park through this authorization to the study sponsor, government agencies, or others may be further disclosed by them, as the health information will no longer be protected by the federal privacy laws.

Statement of Investigator/Person Conducting the Informed Consent Discussion:

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained and that any questions about this information have been answered. A signed copy of this consent will be given to the participant or their legally authorized representative.

SIGNATURE_____ **DATE**_____ **TIME**_____

PRINTED NAME _____

Participant's Statement of Consent:

By signing below, you agree that:

- You have been told of the reasons for this study.
- You have had the study explained to you.
- You have had all of your questions answered, including those about areas you did not understand, to your satisfaction.
- You have carefully read this consent form and will receive a copy of this form.
- You do **not** waive any **legal** rights you have under federal or state laws and regulations.
- You willingly give your consent to voluntarily join in this research study.

Participant/Legally Authorized Representative (LAR):

SIGNATURE_____ **DATE**_____ **TIME**_____

PRINTED NAME _____

Witness Signature is needed in the following circumstances – check below:

☐ Not Applicable
☐ Participant/LAR cannot write – mark must be made as appropriate.
☐ Participant/LAR cannot read - consent has been read to him/her.
☐ Participant/LAR cannot understand English and the consent has been verbally interpreted. (The witness should be fluent in both English and the language of the participant/LAR.)

Witness Statement:

The Participant/LAR has signed this document in my presence.

SIGNATURE_____**DATE**_____ **TIME**_____

PRINTED NAME _____

RELATIONSHIP TO PARTICIPANT_____

CONSENT HANDLING
Original to CRA-Regulatory with Race/ Ethnicity if applicable
Copy to:

- Patient
- CRS registration
- Medical Records