SAFETY

Surveillance After Extremity Tumor Surgery

Informed Consent Guidelines

Version 2.0

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Document History

Date (DD-MMM-YY)	Author(s)	Version No.	Description of Amendment(s)
1-JUN-20	Tricia Schneider	1.0	Initial Version
05-FEB-21	Tricia Schneider	1.1	Addition of 'Managing Patients Who Decline to Participate'
27-JAN-22	Tess Hudson	2.0	Addition of 'When should the participant be approached for consent?'

1.0 Introduction

The purpose of this document is to provide guidance on the informed consent process for the **S**urveillance **AF**ter **E**xtremity **T**umor surger**Y** (SAFETY) trial. Clinical site personnel should review this document prior to beginning study recruitment and refer to it when questions arise. If clinical site personnel have questions regarding informed consent, they should contact the Project Manager at the Methods Center via email and / or telephone.

2.0 Informed Consent

Each site is responsible for developing an informed consent process that meets the requirements of the local ethics committee and Good Clinical Practice. To obtain informed consent, delegated study personnel should follow the procedures below:

- Present the study information in a manner that is understandable to the potential participant / legally authorized representative (proxy);
- Discuss the study with the potential participant / proxy and answer any questions they have;
- Allow the potential participant / proxy an opportunity to discuss participation with their family, friends, or family physician, if desired;
- Confirm that the potential participant / proxy understands the risks and benefits of participating in the study and that their participation is voluntary;
- Complete and obtain signatures on the locally approved Informed Consent Form and obtain contact information from the participant / proxy; and
- Provide the participant / proxy with a copy of the signed Informed Consent Form.

The consent process should take place after surgery and once all active treatments (including radiation and / or systemic therapy) have been completed, the wound has been deemed healed or stable, and the discussion of post-operative surveillance has occurred. Information about the study may be provided prior to surgery, to provide time to review the Information Sheet and prevent undue decision-making stress for patients following the surgical management of a serious, life-threatening disease, thereby likely facilitating an improved consent process. This process minimizes problems of missing patients for a variety of reasons after randomization but prior to the start of intervention.

All eligible patients, or their proxy, should be approached for consent by an authorized member of the local study team within three months of the completion of all active treatment. Consent should ideally occur as soon as possible following the confirmation of eligibility (and once the discussion of post-operative surveillance has occurred) but may take place anytime within this window. The consent process will typically take place in sarcoma clinic during the patient's scheduled post-operative follow-up appointment once all active treatment has been completed and the surgeon approaches the discussion of post-operative surveillance.

Informed consent must be obtained from all patients or their proxy prior to data collection. Informed consent may be obtained via telephone, electronically or in-person, as approved by the local ethics committee. The patient / proxy must be provided with a copy of the signed Informed Consent Form. All sites in Canada must comply with the Personal Information Protection and Electronic Documents Act (PIPEDA), and all sites in the United States of America must conduct

their consent process in accordance with the Health Insurance Portability and Accountability Act (HIPAA). Upon providing informed consent, study participants will be followed for five years from the time of randomization.

3.0 Managing Patients Who Are Hesitant to Participate

Reason for Declining to Participate	Possible Responses
The patient is concerned about not being followed closely enough.	▪ Inform the patient that they can schedule an ad hoc visit at any time, even if it breaks the surveillance protocol to which they are assigned. ▪ Inform the patient that they will be advised on how to self-examine for a local recurrence.
The patient is concerned about too much radiation from CT scans.	▪ If the site investigator typically follows patients with thoracic CT scans every three months, inform the patient that their surgeon's standard of care for surveillance for patients outside of the study is identical to the most intensive study arm.
The patient is concerned about the costs associated with any additional visits.	▪ Inform the patient that parking and / or travel vouchers can be provided to alleviate additional travel costs associated with the study. This is site specific.
The patient believes that the study would cause issues with their insurance coverage.	▪ Inform the patient that all study arms in the 'intervention phase', as well as the 'post-intervention phase', are considered standard of care as per the NCCN guidelines.
The patient believes that the quality of care they would receive would be inferior to what they would receive outside of the study.	▪ Inform the patient that participation in clinical research typically results in superior care, with benefits including especially close monitoring and clinical support, possible access to new treatments / technologies, frequent training of staff, and reduction of resource use when demonstrated to be ineffective / unnecessarily costly.
The patient had a negative experience in a previous research study.	▪ Have a conversation with the patient about their specific concerns and discuss how they may be addressed in this study.
The patient considers the study too burdensome.	▪ If the site investigator typically follows patients every three months, inform the patient that their surgeon's standard of care for surveillance frequency for patients outside of the study is identical to the most intensive surveillance frequency. Inform the patient that the study questionnaires are completed only once

	every six months in the first two years of the study, and once yearly for the final three years of the study duration.
The patient is overwhelmed by their diagnosis.	N/A

4.0 Frequently Asked Questions

This section provides clarification and guidance on the informed consent process. Please contact the Methods Center if you have any questions about consenting a patient to participate in the trial.

4.1 When should the patient be approached for consent?

Patients should not be approached for consent until they are eligible to participate (e.g., wound is healed or stable, radiation and / or chemotherapy are complete, etc.). However, a study Information Sheet may be provided to the participant prior to surgery to give them time to review the information and discuss with their family / friends.

4.2 How can we appropriately obtain consent?

An ideal approach to obtaining patient / proxy consent includes the following steps:

- Allow the patient / proxy to read the Informed Consent Form;
- Explain the key elements of the study (including any additional requirements of the study such as the patient questionnaires) and allow the patient / proxy to ask any questions they may have;
- Ask the patient / proxy to explain in their own words the major items to which they are agreeing; and
- Give the patient / proxy adequate time to make a decision and / or the opportunity to consult with family or friends, if desired.

4.3 How should the consent process be documented?

In addition to documenting consent on the Informed Consent Form, the consent process will be documented on the **Screening Form (Form 1)**. The following steps for obtaining consent will be verified:

- The patient / proxy read the consent / was read the consent; and / or
- The patient / proxy confirmed understanding of the study and had all questions answered; and / or
- The patient / proxy signed the consent prior to completing any study forms; and / or
- The patient / proxy was provided with a copy of the signed consent.

4.4 Should informed consent be reassessed on an ongoing basis?

Informed consent is an ongoing and dynamic process. Initially providing consent does not obligate a participant to continue in the study until its completion. It is considered good practice to confirm that the participant still wishes to continue participating in the study at each visit. Furthermore, the study team is responsible for providing all participants with any new information related to the study interventions or the participants' health condition that may:

- Be relevant to the participants' willingness to continue participation in the trial; and / or
- Adversely affect the rights, safety and / or wellbeing of participants; and / or
- Have an impact on study methodology, conduct, procedures and / or outcomes; and / or
- Alter the ethics committee approval for the study conduct.