



SCREENING FOR SPECIMEN COLLECTION PROTOCOL

I. INTRODUCTION

The purpose/goal of the Specimen Collection Questionnaire is to collect information about the individual with newly diagnosed prostate cancer in order to determine factors that could impact the safety of the subject, any contraindication for blood or fat collection or topical anesthesia injection, or testing results.

II. PROCEDURES

A. Administration

The Specimen Collection Questionnaire will be administered to all study participants by a trained and certified study nurse and conducted as part of the in-home visit. The Specimen Collection Questionnaire will be administered after the Medications Questionnaire and Consent Forms are completed.

B. Materials Needed

1. Specimen Collection Questionnaire
2. Toenail Collection Form
3. Urine Collection Form
4. Body Size Questionnaire
5. Blood Collection Form
6. Fat Collection Form
7. Gel Pen - Black Ink only - Medium Thickness

C. Instructions to the Study Nurse administering the Questionnaire and Forms:

1. Verify participants **ID #** located in the top right hand corner of each page of the questionnaire.
2. Complete the questionnaire using only a **Black Ink GEL pen**, medium thickness. Do not use pencil, felt tip pens or ball point pens.
3. Clearly record the information by printing each letter in the box provided.
4. If an answer is changed, cross out the incorrect answer, initial the change, and fill in the next to the correct answer.
5. If **YES, NO, DON'T KNOW or REFUSED** is answered, place an **“X”** inside the box.

D. General Introduction to Specimen Collection Questionnaire:

Dialogue for the Study Nurse:

Although the tests performed on biologic samples are very important part of the study, you may decline specimen collection. I'm going to ask you some questions to determine whether you can safely donate samples for the study.

E. Specimen Collection Questionnaire and Biological Specimen Collection Procedures with QxQs:

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Prior to collecting specimens, confirm that the consent form has been signed.

- Check 'yes' to indicate that you have done this.
- If the participant did not consent to donate one or more specimens, check 'refused' where indicated at the top of each declined donation form.
- Some patients may decline donations because they are already aware of contraindications; if so, it would be helpful to know this. Therefore, proceed with all of the screening questions, even if the patient declined to donate any or all samples.

1. When was the last time you took anything by mouth other than water?

Date

- Record the numeric value for the month in the first two boxes, followed by the date of the month in the next two boxes, and the year in the last 4 boxes (record all 4 digits, e.g., 2004).

Time

- Record the time according to the time of day when the participant last ate or drank anything other than water.
 - For example, if he last ate at 10 pm the day before the interview, record 10:00 in the text boxes provided and circle 'pm'.

2. Do you have a bleeding disorder?

- Additional explanation: *[If you have a bleeding disorder you would have symptoms like frequent nose bleeds, or very easy bruising, or problems with bleeding after being cut.]*
- The purpose of this question to determine whether blood and/or fat donation would be contraindicated because of the potential for prolonged or severe bleeding, or for excessive bruising.
 - If the participant is unsure if they have a bleeding disorder or if the symptoms they report seem within the normal range (i.e., not compatible with a clinical bleeding disorder) use your judgment about whether blood or fat donation is contraindicated.
 - Continue with the screening questions regardless of their answer, as they may provide additional information to help in determining whether the participant can safely donate blood and/or fat.

- If yes, document the nature of the bleeding disorder below and determine whether to proceed with the blood or fat collection.
- If blood and/or fat collection is contraindicated, check the ‘Contraindication’ box on the appropriate collection forms.
- Record specific bleeding disorders and/or symptoms reported by the participant that may indicate an undiagnosed bleeding disorder. Bleeding associated with use of a blood thinner or anticoagulant medication should be noted in question 3.

3. Do you take Coumadin, Warfarin pills, or other blood thinners?

- If ‘no’ continue to question 4.
- If ‘yes’
 - Record the date and time they last took this medication in the appropriate boxes.
- If ‘don’t know’, check current medications before continuing
 - After checking to see if current medications include blood thinners, check ‘yes’ or ‘no’ in the appropriate boxes. These boxes should be left blank unless ‘Don’t know’ was the initial response to question 3.

NOTE: Use of anticoagulant blood thinners is not automatically a contraindication for blood or fat donation. However, if the participant notes severe bleeding or bruising or other problems giving blood that may be related to the use of anticoagulant medications, blood and fat donation may be contraindicated.

4. Have you ever had problems giving blood?

- Additional explanations (if needed):
 - Have you ever gotten dizzy or faint, or have you ever lost consciousness, fainted or “passed out” when you were having a blood sample taken?
 - If ‘yes’ try to determine the severity of the problem, and use your judgment in deciding whether blood or fat donation is contraindicated. Document the nature of the problem in the box provided. Check the “contraindicated” box on the appropriate collection forms.
 - Have you ever had problems with having blood taken from a particular vein?
 - If ‘yes’ ask the patient if another vein might work better, and use that vein if possible for blood donation.

5. Have you ever had an allergic reaction to a local anesthetic?

- Additional explanations (if needed):
 - *Local anesthetics are shots or injections that are given to numb the mouth before dental work, or to numb the skin before stitching cuts or wounds.*
 - *Allergic reactions include severe itching, redness and swelling from the shot. Sometimes people who are allergic will have trouble breathing because of the shot, but this is very rare.*
- If ‘yes’ fat donation is contraindicated. Document the nature of the problem in the box provided. Check the “contraindicated” box on the Fat Collection Form.

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Although the analyses performed on the biologic samples are a very important component of the study, you may decline specimen collection.

Prior to collecting specimens, confirm that the consent form has been signed. Yes

1. When was the last time you took anything by mouth other than water?

Date: / / Time: : am pm

I'm going to ask you some questions that will help me determine whether you can safely donate samples for the study.

2. Do you have a bleeding disorder?

 No

[Additional explanation: If you have a bleeding disorder you would have symptoms like frequent nose bleeds, or very easy bruising, or problems with bleeding after being cut.]

 Yes Don't Know

If yes, document the nature of the bleeding disorder below and determine whether to proceed with the blood or fat collection. If blood and/or fat collection is contraindicated, check the 'Contraindicated' box on the appropriate collection forms.

3. Do you take Coumadin, Warfarin pills, or other blood thinners _____?

 No

If yes...

Last date took meds:

 / /

Last time took meds:

 : am pm Yes Don't Know

Monitor venipuncture site carefully throughout the interview and instruct the patient to leave bandage in place for at least 4 hours.

If don't know, check current medications before continuing.

 Yes No

4. Have you ever had problems giving blood?

 No

[Additional explanation: Have you ever gotten dizzy or faint, or have you ever lost consciousness, fainted or "passed out" when you were having a blood sample taken? Have you ever had problems with having blood taken from a particular vein?]

 Yes Don't Know

If yes, document the nature of the problem below and determine whether to proceed with the blood or fat collection. If blood and/or fat collection is contraindicated, check the 'Contraindicated' box on the appropriate collection forms.

5. Have you ever had an allergic reaction to a local anesthetic?

 No

[Additional explanation: Local anesthetics are shots or injections that are given to numb the mouth before dental work, or to numb the skin before stitching cuts or wounds. Allergic reactions include severe itching, redness and swelling from the shot. Sometimes people who are allergic will have trouble breathing because of the shot, but this is very rare.]

 Yes Don't Know

If yes, check the 'Contraindicated' box on the fat collection form and document the nature of the problem below.

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TRAINING for ADMINISTRATION OF SPECIMEN COLLECTION QUESTIONNAIRE

I. Participants

All study nurses (trainees) will be certified to administer the Specimen Collection Questionnaire.

II. Date and Time Required

All site training sessions are to be scheduled in advance of the administration of the Specimen Collection Questionnaire as part of the in-home visit.

III. Preparation

A. Materials

1. Specimen Collection Questionnaire Protocol
2. Specimen Collection Questionnaire and Forms
3. Gel Pens—Black Ink Only—Medium Thickness

B. Prior Preparation by trainees

1. Read Specimen Collection Questionnaire Administration Protocol.
2. Read over the Procedures for Certification.

IV. Training

A. Mock Administration of Specimen Collection Questionnaire and Forms

B. Review administration of protocol

1. Introduction
2. Procedures
 - a. Administration
 - b. Materials
 - c. Instructions to Study Nurse
 - d. Introduction to Specimen Collection Questionnaire and Forms

C. Specimen Collection Questionnaire and Forms completion