

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
(AND SAN FRANCISCO GENERAL HOSPITAL )  
CONSENT TO BE A RESEARCH SUBJECT**

**Study Title: RTOG 0232: A Phase III Study Comparing Combined External Beam Radiation and Transperineal Interstitial Permanent Brachytherapy with Brachytherapy Alone for Selected Patients with Intermediate Risk Prostatic Carcinoma**

**PURPOSE AND BACKGROUND**

Dr. Mack Roach and associates from the University of California San Francisco (UCSF) Comprehensive Cancer Center and Dr. Judith Luce and associates from the San Francisco General Hospital (SFGH) are conducting a research study to compare the effects of two investigational treatments in patients with prostate cancer: the effects of placing small radioactive pellets (seeds) inside your prostate (brachytherapy) after external radiation therapy will be compared to the effects of using brachytherapy alone in patients with prostate cancer. You are being asked to participate in this study because you have intermediate risk prostate cancer and combined external beam radiation and brachytherapy or brachytherapy alone are options that has been recommended by your doctor(s). The Radiation Therapy Oncology Group (RTOG) and the National Cancer Institutes (NCI) sponsor this study.

The purpose of this study is to compare the effects (good and bad) of two different radiation treatments in patients with prostate cancer. This research is being done to see which treatment is better. In addition, this study will look at biologic factors that may help to predict and treat prostate cancer in the future. This study will also gather information about the effects of the treatment on your sexual function (potency), urinary function, and on your overall quality of life. A cost comparison between the two treatments, including long term cost thereafter, is also planned for participants under Medicare.

About 586 patients will participate in this study nationwide. About 27 patients will participate in this study at UCSF and SFGH. All procedures will occur at the clinics at UCSF Comprehensive Cancer Center or SFGH.

**PROCEDURES**

You will be “randomized” into one of the study groups (arms) described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group.

**Treatment Arm 1: External Radiation Therapy and then Brachytherapy**

**External Radiation Therapy:**

If you are randomized to receive this treatment, external radiation therapy to your prostate will be given once a day, five days a week, Monday to Friday, for five weeks. External radiation therapy treatments will be given on an outpatient basis at your institution or at UCSF.

### Radiation Therapy:

Prior to starting external beam radiation therapy, you will have at least 2 treatment planning visits. You may also have another CT scan done specifically for radiation treatment planning if the scan you had done for tumor evaluation is not compatible with the radiation treatment planning system. The first visit, called simulation will take about 60 minutes to complete. For this visit you will lie on a treatment table while the radiation therapy staff moves you into the treatment position. A series of measurements will be taken so that you are positioned in exactly the position needed for treatment. You will also receive semi-permanent markings on your chest called "tattoos" designed to help in proper position alignment during each treatment. Following your simulation appointment, you will return to the radiation oncology department for another appointment called a "verify" appointment. During this appointment, all of the positioning calculations will be rechecked so that treatment may begin. This visit usually takes no longer than 30 minutes. Once you begin radiation treatment you will be asked to lie on the treatment table for about 15 minutes for each treatment. A liquid medicine, called carafate suspension, will be given to you to take to lessen the side effects of the radiation therapy. You will need to take the medicine at least 2 hours before or after. This medication is considered standard and is not experimental.

### Brachytherapy:

Two to four weeks after the completion of external radiation therapy, radioactive seeds will be implanted into your prostate. This procedure is done on an outpatient basis under anesthesia at your institution or at UCSF.

### Procedures are done to deliver brachytherapy:

- **Local or General Anesthesia:** During general anesthesia, you will be asleep during the procedure. An anesthesiologist will be monitoring you during the procedure. However, if you have medical conditions and are not able to have general anesthesia then the procedure will be done under local or regional anesthesia. Local anesthesia is a procedure where medication will be injected around the prostate so that the region will be numbed during the procedure.
- **Regional Anesthesia:** A spinal anesthesia, where small needle will be used to inject medication near the spine and you will be numbed from waist down during the procedure.
- With the help of ultrasound, thin needles with radioactive pellets will be inserted through the skin between your anus and scrotum into your prostate.
- As each seed is placed in the correct position, the needle is pulled out leaving the seed in your prostate.

The number of needles and seeds varies depending on the size and shape of your prostate.

### Treatment Arm 2: Brachytherapy Alone

This treatment group will receive the same Brachytherapy as treatment group 1 except that the radioactive seeds will deliver a somewhat higher dose of radiation.

#### Treatment Arm 1 and 2:

If you take part in this study, you will have the following tests and procedures:

- A physical examination, including a digital rectal exam (DRE):
  - prior to beginning treatment,
  - weekly in Group 1 during external radiation therapy (NOTE: DRE is optional/at study doctor's discretion);
  - at 4, 6, 9 and 12 months for the first year following treatment, (NOTE: at 4 months DRE is optional/at study doctor's discretion);
  - every 6 months for the next four years;
  - and then annually for the rest of your life.

The follow-up visits generally take 15 to 30 minutes (in addition to time for answering questionnaires described below).

- Blood tests prior to beginning treatment; weekly during radiation therapy if your doctor feels these tests are needed, and at each follow-up visit (except at the 4 and 9 months visits) as described above.
- An ultrasound examination of your prostate prior to brachytherapy. This is a brief, outpatient procedure in which an ultrasound probe is placed into your rectum to determine the precise size and shape of your prostate. This procedure determines where each needle and seed will be placed.
- Your doctor may want an examination of your bladder prior to treatment. This may include insertion of a small flexible tube through your penis into your bladder (cystoscopy).
- CT scan, MRI, or possible removal and biopsy of pelvic lymph glands, if indicated, to evaluate your cancer prior to treatment.
- If your disease worsens, your physician may request a needle biopsy of your prostate to see how your prostate has responded to treatment.
- A CT scan of your prostate, a pelvic x-ray, and two chest x-rays 3 to 5 weeks following radioactive seeds being implanted.
- You will be asked to complete four questionnaires about your sexual and urinary functioning and overall quality of life. These questionnaires should take about 25-30 minutes to complete. You will be asked to complete these forms prior to treatment, at 4 months, 12 months, and 24 months after treatment and once a year after that for three years.

Digital Rectal Exam is a procedure where the doctor feels the prostate through the rectum. This will take about less than a minute.

An ultrasound examination prior to brachytherapy is a brief outpatient procedure in which an ultrasound probe is placed into the rectum to determine the precise size and shape of the prostate. This procedure determines where each needle and seed is placed. This type of ultrasound is called a **Transrectal Ultrasonography (TRUS) with biopsy**. An image of the prostate is obtained as you simply lie on your right or left side on an examination table. A small probe, the size and shape of an index finger and covered with a rubber shield, is gently inserted into the rectum. You will feel a sensation similar to the one you experienced when you have your rectal examination. Your doctor will

then perform a prostate biopsy, which can be obtained accurately with the guidance of ultrasound. The biopsy is performed through the rectum with a needle. No numbing medicine is necessary for this procedure since the needle is thin and the rectal wall is not sensitive to pain. You may feel some pressure, however, or experience a mild stinging sensation in the prostate when the doctor performs the biopsy. You can leave immediately after the procedure. You will need to avoid heavy exercise or pressure (bicycle riding, etc.) or sexual activity for 24 hours. You may notice some blood in your urine, stools, or semen for several days. You will need to take all of the antibiotics even if you have no symptoms. If you develop a fever more than 101 degrees with chills or continue to have large amount of blood in your urine, stool, it is important that you notify your physician immediately or come to the hospital emergency room.

A CT scan is a type of x-ray that allows your doctors to see inside your prostate to observe the size of your tumor. For the CT scan, you may be given a "contrast material" (like a dye) to drink, an IV (intravenous) line may be started by a needle stick in the arm and a "contrast material" may be injected through the line, or you may receive a rectal contrast (less likely). The I.V. contrast material is a special dye used to get clearer pictures of your body cavity. The oral contrast material is used to help outline the stomach and intestines. The rectal contrast fills up the loops of your lower bowel so the doctors can better visualize your tumor. You will lie flat on a table that will move you into the CT scan machine. You will be asked not to move and may be asked to hold your breath for a few seconds. The CT scan is done in the radiology department and takes about 30 minutes. The CT scan is considered a part of your standard medical care.

Prostate Biopsy: At the time of your initial diagnosis, you had a prostate biopsy done outside of this study and your study doctor will need to obtain a piece of that tissue sample for this study, which will be stored for future research (see Biologic Studies below). Your doctor may also use the results of procedures done outside of this study to check to see if you are eligible for this study. This involves tumor that has already been removed and will not require you to have another prostate biopsy.

Biologic Studies: As mentioned above, some of your tumor tissue obtained from any prostate biopsies outside of this study will be used in the future for research purposes. These tissue samples may be used to learn more about how cancer develops and/or may result in new products, tests or discoveries. In some instances, these may have potential commercial value. These samples to be kept for research purposes will be obtained only at the same time as you undergo procedures done outside of this study; you will not have to undergo any special procedures for this purpose. There will be no additional charge, and you will not receive any payment or financial benefit from any products, tests or discoveries. You may also be asked in the future if you are willing to be in additional research studies. You will not be told the results of any future research. Participation in this extra research is voluntary, and if you choose not to allow the extra research it will in no way affect your care on the main study. You may at any time contact the researchers to ask that your samples are withdrawn from research use, and any identifiable samples still in their possession will be returned or destroyed. Please indicate whether you are willing to allow this extra research by initialing one of the lines at the end of this consent form.

Prostate Re-Biopsy: If, at any time, your disease worsens, your physician may request a needle biopsy of the prostate to see how the prostate has responded (by your own doctor as part of your routine medical care), just as you did at the time of your diagnosis.

## **A. RISKS/DISCOMFORTS**

Randomization: You will be assigned to a treatment group by chance. The treatment you receive may prove to be less effective or to have more side effects than the other study treatment[s] or than other available treatments. This will not be known until after the study is completed and the data has been analyzed.

For the following treatments, "very likely" events are expected to happen to more than 40% to 80% of patients, "less likely, but serious" events will probably happen to less than 1-5% of patients, and "less likely" events will probably happen to less than 5% of patients.

### **Risks Associated with Implant Therapy**

#### Very Likely (50%-80%)

- Infection that can be treated with antibiotics
- Soreness in the implant area
- Temporary fatigue
- Temporary nausea
- Temporary diarrhea
- Abdominal cramps
- Bladder irritation with some bleeding
- Inability to achieve an erection (permanent)
- Urinary Tract Infection (UTI)

#### Less Likely, But Serious (< 5%)

- Injury to the bladder, urethra, bowel or other tissues in your pelvis or abdomen
- Rectal bleeding that requires medication or burning/cutting of tissue or surgery to correct
- Intestinal or urinary obstruction
- Inability to control urination
- Movement of a radioactive seed to the lungs (seed movement away from the prostate has been seen in only 1%-2% of patients receiving seed implants and has never been shown to be of any clinical significance) (permanent)
- Serious infection
- Rectal fistula (breakdown of tissue between the urinary tract and rectum)

### **Risks Associated with Low Dose External Radiation Therapy**

#### Very Likely (40%-60%)

- Tanning or redness of skin in treatment area
- Rash, itching or peeling of skin
- Temporary hair loss in the treatment area
- Temporary nausea
- Temporary diarrhea
- Abdominal cramps
- Bladder irritation with a stinging sensation
- Frequency or urgency of urination
- Inability to control urination (incontinence)
- Rectal irritation with more frequent bowel movements
- Fatigue
- Urinary Tract Infection (UTI)

- Inability to achieve an erection (permanent)

Less Likely, But Serious (< 5%)

- Injury to the bladder, urethra, bowel or other tissues in your pelvis or abdomen
- Intestinal or urinary obstruction
- Rarely, rectal bleeding that requires medication or burning/cutting of tissue or surgery to correct

**Risks Associated with External Radiation Therapy and Seed Implant Therapy**

- Worsening of bowel, bladder, or sexual dysfunction problems
- An overall decrease in your quality of life

Prostate Biopsy: If you are taking blood thinners, such as aspirin, persantine, or coumadin, you should notify your doctor prior to the TRUS/biopsy. The medicines may cause serious bleeding complications after the biopsy, and will need to be stopped at least one week before the biopsy. Even without being on these medications there is a small (< 5%) but real risk of bleeding from the biopsy site. Other risks include pain associated with the procedure, and infection despite the administration of antibiotics.

Transrectal Ultrasound: This is an exam involving sound waves. If you are taking blood thinners, such as aspirin, persantine, or coumadin, you should notify your doctor prior to the TRUS/biopsy. The medications may cause serious bleeding complications after the biopsy. Even without being on these medications there is a small (< 5%) but real risk of infection or bleeding from the biopsy site.

Contrast Risks: The risks of the contrast material used with the CT scan or PET scan include allergic reactions, which are rare, nausea and flushing, and can sometimes be complicated by low blood pressure, asthma, stroke, and organ damage. If the contrast material is given by IV, it may make you feel flushed and give you a sensation of “pins and needles” for a few seconds. Because the contrast material is removed from the body through the kidneys, you may have a CT scan without contrast material if you have kidney problems.

Blood Drawing: The risks of drawing blood include temporary discomfort from the needle stick, bruising, and, rarely, infection.

Post-Treatment Needle Biopsy Risks: If you should require a biopsy after treatment (brachytherapy), the risks include bleeding, pain, possible infection, and rarely, creation of an abnormal opening or passage (fistula).

Reproductive Risks: Because radiation in this study can affect an unborn baby, you should not father a baby while on this study. You may ask your radiation doctors) about counseling and more information about preventing pregnancy.

Sexual and Urinary Function and Quality of Life Questionnaires: There are no serious medical risks to completing the questionnaires. Some of the questions may be too personal and cause you to feel uncomfortable. You may decline to answer any or all of the questions.

Unknown Risks: The experimental treatment[s] may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in this study.

Confidentiality: Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Your study records will be kept by the study doctor and by RTOG (study sponsor) in a carefully guarded computer file at RTOG. Representatives from University of California San Francisco (UCSF), the National Cancer Institute (NCI), the Food and Drug Administration (FDA), Radiation Therapy Oncology Group (RTOG) and other groups or organizations that have a role in this study may review information about you to check on the study. You will be assigned a case number and your full name will not be linked to the number in the RTOG database. Your name will never be used in any published reports about the study.

The study doctors and staff may want to review your medical records from all health care providers outside of UCSF who examine and/or treat you for cancer. If they do, you will be asked to sign a medical records release form for each such health care provider. Once your medical records from outside health care providers are received by UCSF, they become part of your UCSF medical record, and are therefore available for review by all groups mentioned above.

Treatment and Compensation for Injury Policy: If you are injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at (415) 476-1814 or write: Committee on Human Research, Box 0962, UCSF, San Francisco, CA 94143.

## **BENEFITS**

The potential benefit to you is that the treatment you receive may prove to be more effective against your disease than the other study treatment or than other available treatments and/or the treatment you receive may prove to have fewer side effects than other treatments; however this cannot be guaranteed.

## **ALTERNATIVES**

You may choose to not participate in this study. Other treatments that could be considered for your condition may include the following: 1) external radiation therapy alone, whether standard, three dimensional conformal, or intensity modulated radiation therapy (IMRT); 2) internal radiation therapy (seed implants or brachytherapy) like this study, or by temporary insertion of radioactive rods, called high dose rate therapy; 3) hormone therapy; 4) surgery to remove your prostate (radical prostatectomy); or 5) watchful waiting with regularly scheduled monitoring with digital rectal exam (DRE) and PSA blood draws; or 6) You could also choose to have no treatment except medications to make you feel better. With this choice, your tumor could continue to grow and your disease would likely eventually spread. The treatments (1) through (4) could be given either alone or in combination with each other.

Your radiation doctor(s) can tell you more about your condition and the possible benefits of the different available treatments.

A Data Safety Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. Your radiation doctor(s) will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

## **COSTS**

Taking part in this study may lead to added costs to you or your insurance company. If you are randomized to receive Treatment Group 1, the combination of external radiation with implant may result in higher costs to you or your insurance company than an implant alone. The required tests are done more frequently because you are in the study, so these additional tests may increase your medical bills although the impact will be dependent on your insurance company. Insurance companies and other third party payers for health care have sometimes refused to pay for the costs of treatment for patients on research studies, in which case you will be responsible for all costs. Before you decide whether to participate in the study, you may discuss the cost of your care with a financial counselor from the hospital Accounting Department and/or a representative of the Department of Radiation Oncology. Your radiation doctor(s) will obtain pre-authorization (approval to be treated on this program) from your insurance company before you begin treatment. If you have questions about this, you should contact your insurance carrier. The costs of other medical care are your responsibility. No other reimbursement is available. Financial counseling will be available through the University of California of San Francisco Accounting Department, if desired.

## **REIMBURSEMENT/PAYMENT**

You will not be paid for participating in this study, but you will be reimbursed for your parking for the study visits. The study visits that will be paid for include the radiation therapy treatments, the follow-up visits: 4 months, 6 months, 9 months, 12 months, 18 months and 24 months. Parking stickers will be given to you one day prior to your radiation treatment. As for the follow-up visits, parking stickers will be mailed a week prior to your scheduled follow-up visits.

## **QUESTIONS**

This study has been explained to you by the doctor who has signed below or by Dr. Mack Roach, the principal investigator, and your questions were answered. If you have any other questions about the study, you may call Dr. Mack Roach or his associates at (415) 353-7175. If you have questions about your rights as a research participant, you can call the Committee office between 8:00 AM and 5:00 PM, Monday to Friday, by calling (415) 476-1814, or by writing: Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.

## **CONSENT**

You have been given copies of this consent form and the UCSF Subject Authorization for Release of Personal Health Information for Research and the Experimental Subject's Bill of Rights to keep.

**PARTICIPATION IN RESEARCH IS VOLUNTARY.** You have the right to decline to participate or to withdraw at any point in this study without jeopardy to your **medical care**. You may be removed from this study if your disease becomes worse, if side effects become very severe, or if developments occur that indicate the research study is not in your best interest.

**You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.**

\_\_\_\_\_  
Subject's Printed Name

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician Obtaining Consent

\_\_\_\_\_  
Date

**Pathology tissue release:** If you wish to participate, you should initial below.

\_\_\_\_\_  
Initials

The researchers **may keep** my tumor tissue samples for future research. \*

\* If you agree to allow the use of your tissue, please read and sign the attached consent for Use of Tissue for Research (Appendix IB)

\_\_\_\_\_  
Initials

I **do not want** my tumor tissue samples used for any future research.

**APPENDIX IB**

**CONSENT FORM FOR USE OF TISSUE FOR RESEARCH**

## **ABOUT USING TISSUE FOR RESEARCH**

You have had or will have a biopsy (or surgery) to see if you have cancer. Your doctor has removed or will remove some body tissue to do some tests. The results of these tests will be given to you by your doctor and will be used to plan your care.

We would like to keep some of the tissue that is left over from that biopsy for research. If you agree, this tissue will be kept and may be used in research to learn more about cancer and other diseases. The research that may be done with your tissue is not designed specifically to help you. It might help people who have cancer or other diseases in the future.

All possible methods will be used to ensure your privacy and confidentiality. Identifying information will be taken off anything associated with your tissue before it is given to a researcher. Reports about research done with your tissue or blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an affect on your care.

## **THINGS TO THINK ABOUT**

The choice to let us keep the left over tissue for future research is up to you. **No matter what you decide to do, it will not affect your care or participation in the primary study.**

If you decide now that your tissue can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue used and any tissue that remain will no longer be used for research; or, you may request that your tissue, and then any tissue that remains will no longer be used for research.

In the future, people who do research may need to know more about your health. While the University of California, San Francisco or your cancer doctors may give them reports about your health, your name, address, phone number, or any other information that will let the researchers know who you are will not be given.

Sometimes tissue is used for genetic research (about diseases that are passed on in families). Even if your tissue is used for this kind of research, the results will not be put in your health records or reported to insurance companies.

Your tissue will be used only for research and will not be sold. The research done with your tissue may help to develop new products in the future, but you will not be paid for this use.

## **BENEFITS**

There will be no direct benefit to you. The benefits of research using tissue include health providers possibly learning more about what causes cancer and other diseases, how to prevent them, and how to treat them, which may benefit cancer patients in the future.

## **RISKS**

The greatest risk to you is the loss of confidentiality or release of information from your health records. The study doctors and the University of California, San Francisco, will protect your records so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small.

**MAKING YOUR CHOICE**

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". **No matter what you decide to do, it will not affect your care.** If you have any questions, please talk to your doctor or nurse, or call the National Cancer Institute's Cancer Information Service at 1-800-422-6237 (1-800-4-CANCER).

1. **My tissue may be used for the research in the current study.**

Yes                      No

2. **My tissue may be kept for use in research to learn about, prevent, or treat cancer.**

Yes                      No

3. **My tissue may be kept for use in research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).**

Yes                      No

4. **Someone from Dr. Mack Roach/UCSF may contact me in the future to ask me to take part in more research.**

Yes                      No

**Please sign your name here after you circle your answers.**

**Participant statement:**

I have read and received a copy of this consent form. I have been given an opportunity to discuss the information with my radiation doctor and or the research associate, and all of my questions/concerns have been answered to my satisfaction. My answers above and my signature below indicate my voluntary participation in this research.

\_\_\_\_\_  
Subject's signature

\_\_\_\_\_  
Date

**Witness statement:**

I have explained to the patient the information in this Use of Tissue for Research consent form and have answered any questions raised. I have witnessed the patient's signature.

\_\_\_\_\_  
Person Obtaining Consent

\_\_\_\_\_  
Date

**APPENDIX IC**

**CONSENT FORM FOR USE OF COST DATA FOR RESEARCH**

**ABOUT USING COST INFORMATION FOR RESEARCH**

In comparing different treatments for prostate cancer, very little is known about long-term costs of different kinds of treatment. This study compares two different kinds of treatment that are different in their initial costs. However, the long-term costs of two different treatments are not known. Obtaining this information would allow us to study both the cost and the benefits of the treatments involved in this study. This information would help patients; physicians and providers make more informed decisions about these therapies in the future.

We would like to obtain information about both the short-term and the long-term costs of treatment for your prostate cancer. To do this, we would like to use computerized information from the Medicare system to estimate the costs of your medical care. You are being asked to provide your name and Social Security Number so that we may link your treatment and outcomes to the cost data involved in both your treatment and follow-up care.

The information is private and confidential. We must have your permission to use a personal identifier to obtain your specific Medicare information. The specific information about you that is collected will not be given to any other party, including your physician, the hospital, or any other third party. These reports will not be put in your health record. The Medicare data will be aggregated with data from all patients participating in this portion of the study, and only reported in aggregate form. No personal identifying information will be made public.

This cost information will be used only for research.

**THINGS TO THINK ABOUT**

The choice to let us have access to your Medicare information is up to you. **No matter what you decide to do, it will not affect your care or participation in the primary study.**

If you decide now that your Medicare data may be used for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your information, and your information will be removed from the study database.

**BENEFITS**

The benefits of research using cost data include learning how to achieve the most effective treatments for cancer while avoiding added costs and decrease quality of life for patients. This information would help patients like you; physicians and providers make more informed decisions about these therapies in the future.

**RISKS**

There is a very small chance that information from your billing information could be incorrectly released. If you give your permission for us to use your Medicare information, that information will be furnished to the RTOG directly by Medicare, and will not be made available to any third party, including your physician, hospital, employer, or other insurer. All possible methods will be used to protect your privacy and ensure confidentiality.

**MAKING YOUR CHOICE**

If you have any questions about the research involving your cost data or about this form, please talk to your doctor or nurse, or call the National Cancer Institute’s Cancer Information Service at 1-800-422-6237 (1-800-4-CANCER).

Please read each statement below and think about your choice. After reading each statement, circle “Yes” or “No.” **No matter what you decide to do, it will not affect your care** or participation in the primary study.

**My Medicare data may be used for the research in the current study.**

**Yes**

**No**

**Participant statement:**

I have read and received a copy of this consent form. I have been given an opportunity to discuss the information with my doctor/nurse, and all of my questions/concerns have been answered to my satisfaction. My answers above and my signature below indicate my voluntary participation in this research.

\_\_\_\_\_  
Subject’s signature

\_\_\_\_\_  
Date

**Witness statement:**

I have explained the information in this consent form to the patient and have answered any questions raised. I have witnessed the patient's signature.

\_\_\_\_\_  
Person Obtaining Consent

\_\_\_\_\_  
Date