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RUTGERS
Cancer Institute
of New Jersey
RUTGERS HEALTH

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: A Phase II Prospective Clinical Trial to Assess the Feasibility of Preoperative Radiation Boost in Breast Cancer Patients

Protocol Number: CINJ 042005

IRB Number: Pro2020001306

Principal Investigator: Bruce Haffty, MD
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STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to establish the safety of delivering a part of the radiation treatment before breast surgery. If you take part in the research, you will be asked to get a breast Magnetic Resonance Image (MRI) prior to the planning of the radiation treatment. You will also start a part of the radiation treatment before surgery; the standard of care is to receive radiation after the surgery. You will also be asked for a blood sample at the start of the study and to fill surveys assessing your quality of life and your opinion on your breast cosmetic outcomes. Your time in the study will take approximately 3-4 years of participation. You can decide to quit at any time. For the study, you will be required to have a breast MRI which may or may not be required if you are not on the study; that is around a 2-3 hour

appointment. The radiation treatments will be the same duration and time like they would be if you were not on the study but the order of the treatment sessions with respect to surgery will be different. The initial consultation visit and each follow up visit may take an additional 10-15 minutes for you to fill out surveys related to quality of life and cosmetic outcome assessments.

Possible harms or burdens of taking part in the study may be an increased risk of wound complications after surgery.

Possible Benefits of taking part in the study are possible better cosmetic outcome and tumor control with the better targeted radiation treatment to the tumor. Other benefits also include advancing the knowledge of breast cancer response to radiation treatment.

An alternative to taking part in the research study, your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. Bruce Haffty is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

- Dr. Bruce Haffty may be reached at 732-235-2465;

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: Rutgers Cancer Institute of New Jersey

Why is this study being done?
This study is being done to determine the safety of using a new schedule of radiation treatment. The standard of care is delivering radiation treatment to the whole breast after surgery followed by a boost (additional radiation) to the tumor bed which is the area where the tumor used to be. In this study, we want to deliver this boost part before the surgery when we can still visualize the

tumor on imaging. Because we can still visualize the tumor, we will be able to target the tumor better and minimize the radiation that the normal breast tissue would receive. By doing so, we may achieve better cosmetic outcomes and possibly better tumor control. We will also be able to study the biology of the tumor before and after radiation which may help guide future breast cancer research. This study also aims to determine if this radiation schedule improves your experience during the treatment period.

Who may take part in this study and who may not?
Women with early stage breast cancer can take part in this study. If you have palpable lymph nodes or metastatic disease, you cannot take part in this study. You have to be willing to participate and adhere to the study protocol. Pre-menopausal women have to have a negative pregnancy test and have to be willing to be on a reliable birth control method for the treatment duration. This study requires an MRI; if for any reason you cannot have an MRI you will not be able to take part in this study.

Why have I been asked to take part in this study?
You have been asked to take part in this study because you have early stage breast cancer and you fulfill the eligibility criteria. Your doctors think that you are a good candidate for this research protocol.

How long will the study take and how many subjects will take part?
We are expecting to consent 108 subjects to enroll 98 subjects on this study. We expect to finish enrollment in 3 years from initiation of the study. Each subject will be followed on protocol for 3 years from the day they finish the last radiation treatment. You will be one of 98 subjects who will be enrolled at the Rutgers Cancer Institute of New Jersey, Rutgers Cancer Institute of New Jersey at University Hospital, RWJ Cancer Center at RWJBH Hamilton, RWJ University Hospital Somerset/Steeplechase Cancer Center, Cooperman Barnabas Medical Center, Community Medical Center, Monmouth Medical Center, Monmouth Medical Center-Vantage Point Infusion Center, Trinitas Regional Medical Center, Jersey City Medical Center, Newark Beth Israel Medical Center, and Clara Maass Medical Center.

What will I be asked to do if I take part in this study?
If you take part in this study, you will first meet with a research nurse/personnel who will go over the eligibility criteria and consent process with you. If you are eligible and interested in taking part in this research, you will be asked to have an MRI prior to starting treatment and a blood sample at any time point. The MRI will be used to better visualize the tumor so that we can define the volume that we need to treat when planning of the radiation treatment. The blood sample is optional and for research purposes only; we may use the blood to look at circulating tumor cells and to study genetic variations. The standard of care for early stage breast cancer

patients is to undergo surgery (lumpectomy or mastectomy); if the patient chooses lumpectomy (breast conserving surgery), the standard is to receive radiation treatment after the surgery. The radiation consists of two phases; the first phase consists of first three weeks where the patient will be treated to the whole breast. The second phase is a “boost phase” which consists of 4 days treating just where the tumor used to be “tumor bed”.
If you enroll in this study; the “boost phase” will be delivered before the surgery. The reason is that, we hypothesize that visualizing the tumor accurately will help us provide more accurate radiation boost plans and may result in less dose to normal tissue. After the boost phase, you will undergo surgery which would be unchanged from the procedure you will have if you are not on the study. Post-surgery, you will continue the adjuvant radiation treatment to the whole breast. If you are deemed to be a candidate for chemotherapy at that time, you will proceed with the chemotherapy after the radiation treatment is completed.

Thus below is a clarified treatment schedule if you choose to enroll on this study:

1. Once you are deemed eligible, you will be scheduled for a radiation planning session
2. Around a week after the planning session you will start radiation treatment
3. You will only receive the “boost part of the radiation mentioned above” which only targets where the tumor is in the breast. It will be a total of 4 days of treatment. Each treatment is around 10 minutes on the treatment table.
4. Once the four days of RT boost treatment are done, you will be scheduled for your operation between 1-3 weeks from the last day of RT.
5. In 3-8 weeks after surgery, you will be scheduled to continue RT to the whole breast with the same dose and schedule like you would if you were not on the trial.

On the day of consultation and on some subsequent follow ups, you will be given surveys to fill. Those surveys will be on your quality of life and your assessment of your breast physical appearance (cosmesis) based on a scale and on your satisfaction with the outcome. We will ask you permission for optional photographs of your breast during the study. This is optional and it will not affect your enrollment on the study. The photographs of your breast can be taken at any time but preferably at baseline and at 2 and 3 year follow up.

What are the risks of harm or discomforts I might experience if I take part in this study?
By taking part in this study, the patient may have a risk of wound complications after surgery. With any surgery, there are risks of wound infections and delayed healing. In this study, the risk of delayed wound healing is slightly higher due to the radiation delivered prior to the surgery. We expect this risk to be low (below 6%).

Patients are free to withdraw from the study at any time. Long term complications are very rare and these include delayed wound healing, long term scarring in the irradiated breast and

radiation side effects. We do not expect these side effects to be significantly different than the standard of care.

The risks associated with the study MRI and blood withdrawal are very low. MRI is an imaging study that we will be using for the treatment planning. The MRI study takes 2-3 hours to be completed and in this case is done mainly for study purposes. If a patient is claustrophobic, they may not tolerate the MRI and may have to be taken off the study.
When your blood is drawn, there may be a bruise, or bleeding, or infection, at the place where your blood is drawn. However, infection is rare.

Radiation is known to be harmful in pregnancy and to cause birth defects. For this reason, no one can be in this study who is pregnant or who could get pregnant while taking the study drug. If you are a woman of childbearing age and you are sexually active, you are asked to use one of the following methods of contraception while taking the study drug: Oral contraceptives, IUD, injected contraceptives. If you are unwilling to use adequate birth control measures, you should not sign up for this study and are asked not to sign this consent form.

If you become pregnant during the treatment course of this study, you should notify the study doctor of this fact as soon as possible, since the risks to the fetus or to yourself are unknown.

You should not take any over-the-counter medicines, herbal products, vitamins or food supplements while taking part in this study, unless you tell the study doctor and get permission from the study doctor to go on taking these medicines. You will follow the instructions of the study doctor about the use of any of these products.

You should also tell the study doctor about all medicines that other doctors may have prescribed for you to take.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be achieving better cosmetic outcome and maybe better local control because of the more accurate targeting of the tumor with radiation. However, this remains a hypothesis for now and it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
Your alternative is not to take part in this study and you will be treated with the standard of care.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

If the MRI reveals any new clinical information that requires changing the treatment paradigm, you will be informed about that.

Will there be any cost to me to take Part in this study?
There will be no cost to you to take part in this study.

Will I be paid to take part in this study?
You will not be paid to take part in this study.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Each patient will be assigned a study number that will be linked to the medical record number on a website that is only accessible to the doctors and study personnel. All patient data will be stored in secure folder in a locked computer to ensure confidentiality.

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

What will happen to my information or biospecimen collected for this research after the study is over?

- ☐ Your biospecimen collected about you for this research will not be used by or distributed to investigators for other research.

What will happen if I am injured during this study?

Subjects in this study may be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment. In addition, it is possible that during the course of this study, new adverse effects that result in personal injury may be discovered.

The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs

is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Bruce Haffty; 195 Little Albany St., New Brunswick, 08901. Radiation Oncology Department. 732-235-5203.
At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I contact if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Dr. Bruce Haffty; Radiation Oncology Department. 195 Little Albany St., New Brunswick, 08901. 732-235-5203.

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: New Brunswick/Piscataway Health Science IRB 335 George St., Liberty Plaza Ste. 3100, New Brunswick, NJ 08901, (732)235-9806.
Or the Rutgers Human Subjects Protection Program at (973) 972-1149, email us at humansubjects@ored.rutgers.edu., or write us at 65 Bergen St., Suite 507, Newark, NJ 07107.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is the Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?
(Tailor the list to reflect only what your study will collect. Collect only what is needed to satisfy study aims and is consistent with what is outlined in the protocol to be collected.)

- All information in your medical record
- Hospital discharge summaries
- Radiology records or images (MRI, CT, PET scans)
- Medical history or treatment
- Medications
- Consultations
- Laboratory/diagnostic tests or imaging
- QOL surveys and cosmetic assessment questionnaires
- Pathology reports, specimen(s) or slide(s)
- Operative reports (about a surgery)
- Emergency Medicine reports
- Follow up data including any recurrence or toxicity encountered

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved in The Study
- Rutgers Cancer Institute of New Jersey
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Hospital Personnel as Necessary for Clinical Care:

- University Hospital
- Robert Wood Johnson University Hospital
- Data Safety Monitoring Board and others authorized to monitor the conduct of the study

Will I Be Able to Review My Research Record While the Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have to Give My Permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind and Take Away My Permission Later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Dr. Bruce Haffty; 195 Little Albany St., New Brunswick, 08901. Radiation Oncology Department. 732-235-5203.

How Long Will My Permission Last?
There is no set date when your permission will end. Your health information may be studied for many years.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print): _____

Subject Signature:_____Date:_____

Signature of Investigator/Individual Obtaining Consent:
To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____Date:_____

FOR NON-ENGLISH-SPEAKING SUBJECTS:
Signature of Reader/Translator If the Subject Does Not Read English Well:

The person who has signed above, _____, does not read English well. You read English well and are fluent in _____ (name of the language), a language that the subject (his/her parent(s)/legal guardian) understands well. You understand the content of this consent form and you have translated for the subject (his/her parent(s)/legal guardian) the entire content of this form. To the best of your knowledge, the subject (his/her parent(s)/legal guardian) understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and these questions have been answered (his/her parent(s)/legal guardian).

Reader/Translator Name: _____

Reader/

Translator Signature:_____ Date: _____

Witness Name: _____

Witness Signature: _____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

ADDENDUM: CONSENT TO PHOTOGRAPH SUBJECTS

Title of Study: A Phase II Prospective Clinical Trial to Assess the Feasibility of Preoperative Radiation Boost in Breast Cancer Patients

Principal Investigator: Bruce Haffty, MD

You have already agreed to take part in a research study entitled: A Phase II Prospective Clinical Trial to Assess the Feasibility of Preoperative Radiation Boost in Breast Cancer Patients conducted by Dr. Bruce Haffty. We are asking your consent to allow us to photograph you as part of the research. You do not have to consent to be photographed in order to take part in the main research.

The photographs will be used for assessing cosmetic outcome by the research team. The photographic images will not be used for commercial purposes.

The photographs will only encompass the breast region; the face will not be photographed in order to protect subjects from being identified.

The photographs will be stored in a locked folder on the PI computer with a link to the subject's ID number. The ID numbers are linked to the MRNs on Oncore. The photographs will be stored until completion of study analysis and will be destroyed upon publication of study results.

The photographs will not be used by us or distributed to investigators for other research.

Your signature on this form permits the investigator named above to photograph you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written consent.

AGREEMENT TO BE RECORDED

Subject Name
(Print):_____

Subject Signature: _____ Date:_____

Investigator/Person
Obtaining Consent Name (Printed):_____

Signature: _____ Date: _____

Addendum: Consent to Store Identifiable Biospecimen and/or Health Information in a Research Repository for Future Research

Title of Study: A Phase II Prospective Clinical Trial to Assess the Feasibility of Preoperative Radiation Boost in Breast Cancer Patients

Principal Investigator: Bruce Haffty, MD

We ask your permission to collect and store blood, tissue, and health information collected about you during the main study A Phase II Prospective Clinical Trial to Assess the Feasibility of Preoperative Radiation Boost in Breast Cancer Patients for future research. Blood for banking will be collected at any point during the study. Tissue will be collected at the time of surgery. Following are details about our request.

Please know that you may still participate in the main study even if you say no to this request to store blood and tissue for future research.

Some of the future research may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment. This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to request the genetic information we get from this research and discriminate against you based on your genetic information.

Following are details about our request. Please know that you may still participate in the main study even if you say no to this request to store blood for future research.

This research involves collection, storage, and analysis of blood samples. Some of these samples are required for you to take part in this study because the research done on the samples is an important part of the study. You will not get health benefits from any of these studies, but they are an important part of the research. The researchers leading these studies hope the results will help other people with cancer in the future. The researchers will not add the results of the studies to your medical records and you or your study doctor will not know the results.

How and where will my blood and health information be stored and by whom?

Your blood and tissue samples will be stored in the Cancer Institute of New Jersey Biorepository. Located at 195 Little Albany Street, New Brunswick, NJ, 08901.

Information obtained from this research with material obtained from your blood and tissue sample(s) will be kept confidential so that neither the investigator nor the Sponsor can link your individual research results with your identity.

Your sample(s), and materials derived from your sample(s), will be given a code number, and only information related to your age, sex, race, health condition and other relevant clinical information collected in the main study will be linked with the sample's code number. Your name, date of birth, address, or other personal identifying information, will not be linked with the sample(s) you give.

The purpose of the repository is to store blood and tissue samples to be used for future research to be conducted by the Principal Investigator and the research staff at Cancer Institute of New Jersey. The goal of the research is to better understand and develop better means to prevent, diagnose and treat disease.

All of the subjects in this study will be asked to allow blood to be stored and used for future use in the repository. Only subjects at CINJ will be asked to allow tissue to be stored and used for future use in the repository. The more samples and health information available in storage, the more useful the repository will be for medical research.

How and what samples will be collected from or about me?
A blood sample will be collected, up to 30ml of blood (3 tubes) and a tissue sample will be collected up to 1g of tissue if you have agreed. This is optional and will not affect your enrollment on the study.

What are the risks of harm or discomfort I might experience if I take part?

Psychological or Social Risks Associated with Loss of Privacy:

Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Further, patterns of genetic variation also can be used by agencies to identify a person or his/her blood relatives (for example, to establish relationships between parents and their children).

Economic Risks of Harm:
Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family economic distress.

There is a federal law call the Genetic Information Nondiscrimination Act (GINA) that helps protect against genetic discrimination. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

What are the benefits of participation?

You will not benefit personally from providing samples for this tissue bank because research usually takes a long time to produce meaningful results. However, your participation may help investigators understand, prevent, or treat the diseases and conditions studied in the future.

How will information about you and your tissue samples be kept private and confidential?
Information obtained from this research with material obtained from your blood or tissue sample(s) will be kept confidential so that neither the investigator nor the Sponsor can link your individual research results with your identity.

Your sample(s), and materials derived from your sample(s), will be given a code number, and only information related to your age, sex, race, health condition and other relevant clinical information collected in the main study will be linked with the sample's code number. Your name, date of birth, address, or other personal identifying information, will not be linked with the sample(s) you give.

Is there other important information to consider?
Yes. There is no cost to you to allow us to store and use your blood and information for future research. Nor will you be paid to participate in this repository. Should any products or services result from research using your samples and information, there is no plan to share any of the profits with you.

The research we are doing is only a stepping stone in understanding disease. It may take a long time for our research to produce useful health-related information. Therefore, tests done for our research using your samples and information will not be useful in directing your medical care. Information from our research will not be returned to you, your family members, your doctor, or outside parties. It is possible, however, that members of regulatory authorities, such as the U.S. Food and Drug Administration, Rutgers University Institutional Review Board, or other persons required by law may be allowed to look at this information.

What are your rights if you agree to the storage and use of your tissue for future research?
You have the right to ask questions about any part of our storage and future research at any time. You should not sign this form unless you have a chance to ask questions and have been given answers to all of your questions. Your participation in this part of the study is voluntary. You do not have to participate. If you do, you can change your mind at any time.

If I Say Yes Now, Can I Change My Mind and Take Away My Permission Later?
Yes, you can write to your study doctor (Bruce Haffty, MD, 195 Little Albany Street, New Brunswick, NJ 08903) and tell him to destroy any remaining blood sample(s) and data of yours that are currently being stored.

However, please note that it may not be possible to destroy samples, information and data created from your samples that may have already been used in research studies prior to your request.

The Cancer Institute of New Jersey will keep records linking your identity with the blood sample(s) indefinitely. Until those records are destroyed, you may ask that your blood sample(s) and materials obtained from your sample(s) be destroyed.

Please tell us if and how you wish your biospecimen and/or information to be used for future research. Please add your Initials to indicate the ways you permit your samples and information to be used:

My blood, tissue, and related information may be stored in CINJ Biorepository for use in future health cancer-related research.

Yes _____ (subject's initials)

No _____ (subject's initials)

Please tell us if we may contact you in the future to tell you about other ways you may participate in this research or other research we are conducting by signing your initials next to your choice.

Yes ____ No _____

Who Can I Contact If I Have Questions?

If you have questions about taking part in this study, you can contact the study doctor:

Bruce Haffty, MD
195 Little Albany Street
New Brunswick, NJ 08903
Tel: 732-235-2465

If you have questions about your rights as a research subject, you can contact the IRB Director at:

New Brunswick/Piscataway Health Science IRB (732)235-9806
or
The Rutgers Human Subjects Protection Program at (973) 972-1149 or email us at humansubjects@ored.rutgers.edu