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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	Phase II Clinical Study of Noni Extract in Men with Very Low Risk or Low Risk Prostate Cancer
PROTOCOL NO.:	Huang 2015-1 WIRB® Protocol #20151535
PROTOCOL VERSION DATE:	February 7, 2017
SPONSOR:	University of Hawaii Cancer Center
INVESTIGATOR:	Charles J. Rosser, M.D., M.B.A., F.A.C.S. 701 Ilalo St., Rm. 327 Honolulu, Hawaii 96813 United States
SUB-INVESTIGATORS:	Jeffrey Huang, Pharm.D.
STUDY-RELATED PHONE NUMBER(S):	Charles J. Rosser, M.D., M.B.A., F.A.C.S. 808-564-5994 808-524-2575 (24 hours) University of Hawaii Cancer Center Clinical Trials Office 808-586-2979

WHO IS DOING THIS STUDY?

The University of Hawaii Cancer Center is sponsoring this trial. Your study doctor has met all requirements to be an investigator (researcher) for the University of Hawaii Cancer Center.

WHY AM I BEING ASKED TO TAKE PART IN THIS STUDY?

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may have a copy of this consent to take home to review as you consider your decision to participate. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in a research study of men with very low risk or low risk prostate cancer who are undergoing active surveillance for their prostate cancer.

WHAT IS THE USUAL APPROACH TO MY STAGE OF PROSTATE CANCER?

Active surveillance (also called watchful waiting, expectant management or deferred treatment) is one way to treat very low risk or low risk prostate cancer. This means that you may have doctor visits every 6 months to check your prostate and PSA (Prostate Specific Antigen). Your doctor may recommend a prostate biopsy if your prostate examination or PSA show that your prostate cancer is getting bigger (progressing).

Other therapy options to consider include radiation therapy (e.g. external beam radiotherapy or brachytherapy), surgery (radical prostatectomy), cryosurgical ablation, and high-intensity focused ultrasound (HiFU).

Many factors need to be considered when deciding on your treatment. Such factors include family history and race, which may be contributing factors to aggressive disease. If you have a family history of prostate cancer, and/or are of African-American descent, more aggressive treatment options may be appropriate. Your study doctor will discuss all available treatment options with you.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your other choices may include:

- You may choose to have the usual approach described above
- You may choose to take part in a different study, if one is available
- Or may choose not to be treated for cancer.

Talk to your doctor about your choices before you decide if you will take part in this study.

WHY IS THIS STUDY BEING DONE?

The fruit of the Noni plant (scientific name is *Morinda citrifolia*) is used in traditional medicines of Native Hawaiians, other Pacific Islanders, and Asian populations, and has been used to treat various diseases such as heart problems, diabetes, high blood pressure, arthritis, and other degenerative ailments. In this study, a Noni extract, made from the dehydrated (dried) fruit and concentrated into a pill form will be studied.

The purpose of the study is to find out if Noni extract taken in a pill/capsule form every day for one year affects your prostate cancer. The study will also look at the effect of Noni on laboratory tests for prostate cancer (PSA, the OncoType Prostate Score and associated genetic expression changes). From questionnaires and doctor visits, the study will look at your quality of life, your urinary and bladder symptoms and any side effects of the Noni extract.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 30 men will participate in this study.

WHAT ARE THE STUDY GROUPS?

All participants in this study will take capsules that contain Noni extract every day for 1 year. There is no placebo group in this study.

HOW LONG WILL I BE IN THIS STUDY?

You will receive the Noni capsules for 1 year.

WHAT TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY?

Before you begin the study:

If you decide to participate, you will be asked to sign this Informed Consent document.

You will need to have the following examinations, tests or procedures to find out if you can be in the study. If you have had some of them done recently, they may not need to be repeated. This will be up to your study doctor. After signing the consent, the following review of your condition will occur:

- A review of your medical records.
- A complete history and physical exam
- A digital rectal exam (DRE) if not done by the study doctor within 6 months prior to enrollment to the study
- A PSA (Prostate Specific Antigen) test if not done within three months of enrollment to the study.
- Review of all your prescription and over the counter medications, including vitamins and other supplements
- Blood tests (complete blood count and blood chemistries, including tests of your liver, kidney function and clotting ability, (about 4 teaspoons of blood)
- MRI of your pelvis if not done within 12 months prior to enrollment to the study
- Obtaining the prostate cancer tissue removed at the time of your biopsy and sending it for the Oncotype DX Prostate test. The Oncotype DX Prostate test is a test that looks at the activity of certain genes in your prostate cancer in order to provide personalized information about how aggressive your cancer is.

If these above items show that you qualify for the study, a research staff person will explain the study to you and if you still wish to join the study, you will be enrolled to the study and will be asked to complete the following:

- Answer a questionnaire called the Lower Urinary Tracts Symptoms (LUTS) survey which asks questions about your current urinary function and bladder habit
- Complete Quality of Life Questionnaires which ask questions as to how you function on a daily basis
- Have your blood samples collected. (about 2 teaspoons of blood)

During the study:

All participants in this study will receive the Noni extract. There is no placebo group or placebo (blank capsules) used in this study. A research staff person will give you the bottles of Noni capsules study. Each study capsule contains 500 mg Noni. The study dose is 6,000 mg (12 capsules) per day in divided doses. You will take it as follows:

- 4 capsules with breakfast
- 4 capsules with lunch, and
- 4 capsules with dinner

The capsules should be swallowed whole with at least ½ to 1 cup of water. If you miss a meal, you may take the capsules on an empty stomach with the same amount of water. If you miss a scheduled dose, do not try to take the missed capsules as a later time. Please note the missed capsules in a pill diary and report it at your next office visit.

From the date that you are given your first supply of study capsules, clinic visits with your study doctor will be at 1, 3 6, 9 and 12 months. At each visit you will be given enough study capsules to last until your next visit up to month 12. If there are no reasons to stop taking the study capsules, you will stop taking the study drug at the end of 1 year (12 months.)

At your 1 month visit the following will be done:

- Review your medical history and be asked if you had any side effects from the Noni
- Review your prescription and over the counter medications, including vitamins and other supplements that you taking
- Blood test to check your bloods clotting ability (about 1 teaspoon)
- Do a count of any remaining Noni capsules that you have
- Receive a new supply of Noni capsules

At the 3-, 6-, 9-, and 12- months visits, the following will be done:

- Review your medical history and be asked if you had any side effects from the Noni
- Review your prescription and over the counter medications, including vitamins and other supplements
- A DRE (digital rectal exam)

- A PSA (Prostate Specific Antigen) test and blood tests (complete blood count and blood chemistries, including tests on your blood's clotting ability, liver and kidney function (about 4 - 5 teaspoons of blood)
- In addition to the above blood collected for the blood count and blood chemistries, extra research blood samples will be collected (about 1-4 teaspoons of blood)
- Do the Lower Urinary Tracts Symptoms (LUTS) survey
- Complete Quality of Life Questionnaires
- Do a count of remaining Noni capsules that you have
- Receive a new supply of Noni capsules (not at the 12-month visit)

At the 12-month visit, these additional items will be done:

- Instructed to stop taking the Noni capsules
- Return any Noni capsules that you have left
- Do a count of remaining Noni capsules
- A physical examination, including height, weight, temperature, pulse and blood pressure
- A DRE (digital rectal exam) and Prostate biopsy (see below)

Prostate biopsy involves the placement of a sound-wave device into the rectum immediately next to the prostate gland. Using this sound-wave (ultrasound) device to look at the prostate as well as a guide, a hollow biopsy needle is used to remove pieces of prostate tissue from the prostate gland. Prostate tissue from the biopsy will be sent to the pathology laboratory for examination and for the Oncotype DX Prostate test.

Seven (7) days after your 12-month visit, research staff will contact you by phone and ask you about the prescription and over the counter medications, including vitamins and other supplements, and if you have any side effects from the Noni.

The tests and procedures at each study visit are summarized in this table:

	Screening	**Baseline**	**Month 1**	**Month 3**	**Month 6**	**Month 9**	**Month 12 or Early Stop**	**7 DAYS AFTER**
Signed Informed Consent	X							
Demographic Questionnaire		X						
Physical Exam	X	X					X	
Digital Rectal Exam (DRE)	X (if not done within 6 months by study doctor)						X	
Signs and Symptoms (Adverse Events)	X	X	X	X	X	X	X	X
Medications	X	X	X	X	X	X	X	X
PSA test	X			X	X	X	X	
Blood Chemistry	X			X	X	X	X	
PT/PTT	X		X	X	X	X	X	
Complete Blood Count	X			X	X	X	X	
Oncotype Dx Prostate test	X						X	
Pelvic MRI with contrast	X (or within prior 12 months)							
Compliance check (pill count and diary)			X	X	X	X	X	
Research Blood Sample Collection		X		X	X	X	X	
Quality of Life Questionnaires		X		X	X	X	X	
Lower Urinary Tract Symptoms (LUTS) Questionnaires		X		X	X	X	X	
Dispense Noni Capsules		X	X	X	X	X		
Prostate Biopsy							X	

- Includes history and physical, height, weight, and a digital rectal examination every 12 months at the urologist's discretion.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

If you choose to take part in this study, there is a risk that you may:

- Lose time at work or home and spend more time in the hospital or doctor's office than usual
- Be asked sensitive or private questions which you normally do not discuss

The treatment used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from your participation in this study.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

What are the Risks of Noni Extract?

There a few known risks from Noni extract. In a previous study with Noni taken as capsules, study participants took about 2 to 3 times the dose of Noni used in this study. The most common side effect was upset stomach or discomfort believed to be related to the number of Noni capsules that were taken for that study, which was up to 7 capsules taken 4 times a day.

Allergic reactions can occur to the Noni extract or other ingredients used in the Noni capsules. Severe allergic reactions can be life threatening.

If at any time, or at the time of your study visits, you report or your study doctor suspects or your blood tests show possible side effects from the Noni extract you may be told to stop taking the Noni capsules. You may be checked every week to see if it is safe for you to continue taking the Noni extract. If you have a serious side effect, or do not recover from any side effects with 30 days, you may be told to discontinue the Noni capsules permanently, and may be taken off the study. The study doctor and/or research staff will continue to monitor or keep in contact with you until side effects resolve.

The risks for having your blood drawn include infection at the site of the blood draw, bruises and swelling, fainting and pain from the leaking of blood from the veins into the skin. Trained staff and sterile tools will be used to minimize potential risks.

Subjects will be assessed clinically (by history and examination) for side effects (adverse events) during screening, prior to enrollment, at all study visits and at the end of 1 year. Blood tests will be done as described previously to check for possible side effects on your blood count, liver and kidney function.

The prostate biopsy can be uncomfortable and can cause bleeding in the urine or rectum or blood-tinged ejaculate (body fluid released by the prostate during sexual intercourse). There is also a risk of temporary inability to urinate or have infection.

The MRI may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the MRI. Temporary hearing loss has been reported from this loud noise. You may be asked to wear ear protection. At some time during the test, you may be asked to hold your breath for a while, which can be uncomfortable. Because potential risks to a fetus from a MRI are unknown, pregnant women must not have a MRI.

The effects of electromagnetic fields (EMF) on the human body are not well understood. There is a very small possibility that this exposure from the MRI could have a bad effect such as causing some form of cancer. The exposure in this study is not expected to greatly increase EMF risks, but the exact increase is unknown.

If your prostate cancer changes from very low risk or low risk prostate cancer you will be told and you and your doctor will discuss treatment recommendations. It may be possible during the conduct of this study that a prostate biopsy is recommended due to changes in your PSA or prostate examination.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

It is not possible to know at this time if taking Noni is better than the usual approach of surveillance. This study may or may not help you. This study will help researchers learn things that may help people with very low or low risk prostate cancer in the future.

CAN I STOP TAKING PART IN THIS STUDY?

Yes, you can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor or sponsor may take you out of the study at any time without your consent for any reason including:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, Institutional Review Board (IRB) or Federal Drug Administration (FDA)
- If you do not consent to continue in the study after being told of changes in the research that may affect you.
- If you have a medical condition not observed at the time of screening and baseline tests that may have disqualified you
- If your DRE and/or PSA results show possible worsening of your prostate cancer (no longer very low risk or low risk prostate cancer)
- At the discretion of the investigator

Hawai'i Cancer Consortium partners do not urge, influence, or encourage anyone who works for participating hospitals or the University of Hawai'i Cancer Center to take part in a research study. Your participation in this study is completely voluntary. You may withdraw from the study at any time and for any reason. Your decision to not participate in the study, or a decision on your part to withdraw from the study, will have no affect whatsoever on your employment status. You may refuse to participate or you may withdraw from the study at any time without penalty or prejudice.

WHEN I AM FINISHED PARTICIPATING IN THIS STUDY

After you have completed the study, you will continue with your usual care for prostate cancer.

WHAT ARE MY RIGHTS IN THIS STUDY?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty or loss of benefit to which you are otherwise entitled. You will not lose medical care or any legal rights.

For questions about your rights while in this study, you may call the Western Institutional Review Board at 800-562-4789. You may also contact the Principal Investigator, Charles J. Rosser, M.D., M.B.A., F.A.C.S. at 808-564-5994, or 808-524-2575 (24 hours), or the University of Hawai'i Cancer Center at 808-586-2979.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

The study agent (Noni capsules) will be supplied at no charge while you take part in this study.

The study will be billed for charges related to research (example PSA at 3 and 9 months, research blood draw).

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of managing any side effects. Procedures that are standard of care will be billed to your insurance. The 12 month oncotyping lab test will be paid for by the study. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You are responsible for all co-pays and deductibles as you normally would be. If you belong to a Medicare Advantage Plan, your claims while on this study will be billed to the regular Medicare and you may have a higher co-pay.

You may have transportation costs as part of your participation in this study. Please talk to the Principal Investigator or your study doctor if you need assistance with transportation costs during your participation in this study. Assistance may be available.

WILL I BE PAID FOR BEING IN THE STUDY?

You will not be paid for taking part in this study.

WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS STUDY?

It is important that you tell your study doctor, or the Principal Investigator, Charles J. Rosser, M.D., M.B.A., F.A.C.S. if you feel that you have been injured because of taking part in this study, if you require treatment for any injury or illness related to procedures required by the study, or if you suffer side effects while in the study. You can tell your doctor in person or call Dr. Charles Rosser at 808-564-5994 or 808-524-2575 (24 hours).

The study has no plans to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you will be responsible for any costs. If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study. You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor
- National Cancer Institute (NCI)
- The Western Institutional Review Board® (WIRB®), a group of people who review the research study to protect your rights
- The University of Hawaii Human Studies Program (UH IRB), the University's review board
- The Food and Drug Administration in the U.S., and government agencies in other countries where the study drug may be considered for approval

USE AND DISCLOSURE OF YOUR HEALTH INFORMATION

By signing this form you are authorizing the use and disclosure of individually identifiable information. Your information will only be used/disclosed as described in this consent form and as permitted by state and federal laws. If you refuse to give permission, you will not be able to be in this research.

The purposes of releasing your protected health information are to collect the data needed to complete the research, to properly monitor (watch) how the study is done, and to answer research questions related to this study.

There is no expiration date to this authorization.

WHAT INFORMATION MAY BE USED AND GIVEN TO OTHERS?

The study doctor will get your personal and medical information. It includes:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about:
    - Physical exams
    - Laboratory, and other test results
    - Questionnaires

- Records about any study drug you received
- Information about other medical conditions that may change your treatment and/or side effects you may have, and how these were treated
- Long-term information about your general health status and the status of your disease
- Future test results from tissue and/or blood samples that may be collected from you
- Numbers or codes that will identify you such as your social security number and medical record number.

MAY I WITHDRAW OR REVOKE (CANCEL) MY PERMISSION?

Yes, but this permission will not stop automatically.

If you choose not to be in the study, choose to withdraw from the study, or if you refuse to sign the authorization, it will not make a difference in your usual treatment, or your payment, and it will not change your eligibility for any health plan or health plan benefits that you are allowed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

WHO MAY USE AND GIVE OUT INFORMATION ABOUT YOU?

By signing this consent form you authorize the following parties to use and/or disclose your identifiable health information collected or created for this study:

- Charles J. Rosser, M.D., M.B.A., F.A.C.S. and his research staff for the purposes of conducting this research study
- University of Hawaii Cancer Center
- The Queen's Medical Center
- Island Urology Oahu LLC
- Island Urology Hilo LLC

Your medical records may contain information about AIDS or HIV infection, venereal disease, treatment for alcohol and/or drug abuse, or mental health or psychiatric services. By signing this consent form, you authorize access to this information if it is in the records used by members of the research team.

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Study information collected about you will be given to the sponsor. "Sponsor" means any persons or companies that are working for or with the sponsor, or owned by the sponsor.

It will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study drug may be considered for approval.

Medical records which identify you and the consent form signed by you will be looked at and/or copied for research, quality assurance, data analysis or regulatory purposes by:

- Representatives of the National Cancer Institute (NCI)
- Federal, state and local agencies having oversight for this research, such as the Office for Human Research Protections in the U.S. Department of Health and Human Services, the Food and Drug Administration in the U.S., the National Institutes of Health, etc.
- The University of Hawaii Human Studies Program, the University's institutional review board
- Western Institutional Review Board® (WIRB®)
- The University of Hawaii Cancer Center

Some of the persons or groups that receive your study information may not be required to comply with federal privacy regulations, and your information may lose its federal privacy protection and your information may be disclosed without your permission.

ACCESS TO YOUR INFORMATION

Your right to access your records that are created or obtained as a part of this research may be temporarily suspended for as long as the research is in progress if the access will potentially affect the outcome of this research study. Your right to access will be restored as soon as this study is completed or when granting you access will not affect the outcome of this study.

By signing this consent form, you will not give up any legal rights.

WHERE CAN I GET MORE INFORMATION?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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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.

You will get a copy of this form. If you want more information about this study, ask your study doctor.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

You can talk to your study doctor about any questions, complaints, or concerns you have about this study. Contact your study doctor or Principal Investigator, Charles J. Rosser, M.D., M.B.A., F.A.C.S. at 808-564-5994, or 808-524-2575 (24 hours) for any of the following reasons:

- If you have any questions about this study or your part in it, or
- If you feel you have had a research-related injury or bad reaction to the study drug.

Contact the University of Hawaii Cancer Center at 808-586-2979 for any of the following reasons:

- If you have any questions about this study or your part in it, or
- If you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, WA 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
Email: Help@wirb.com

WIRB® is a group of people who perform independent review of research.

WIRB® will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB® if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

OPTIONAL RESEARCH STUDIES SECTION

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records, nor will you or your study doctor know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say 'no' to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

1. FUTURE CONTACT

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

Yes **No**

(Please circle your choice)

2. MANDATORY BIOBANKING FOR POSSIBLE FUTURE STUDIES

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies 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.

If you choose to take part in this study, the study doctor for the main study would like to collect a sample of tissue from your previous biopsy. Also, if your disease progresses and you and your physician decide you should have a biopsy as part of your usual cancer care, the study doctor for the main study would like to collect a sample of tissue from that biopsy.

The researchers also ask your permission to store and use your samples and health information for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by the University of Hawaii Cancer Center and supported by the National Cancer Institute.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) Your tissue will be collected as described above and will be sent to the Biobank.
2) Your sample and some related information may be stored in the Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up.
3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
2) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
   In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

3) Some states have laws to protect against genetic discrimination. A federal law called the Genetic Information Non-Discrimination Act, or GINA, is in effect. This law helps to lower the risk of health insurance or employment discrimination. The law does not include other types of misuse by life insurance, disability, or long term care insurance. To learn more about the GINA Law, please check the Internet or ask the study staff. You may also call the Hawaii Department of Insurance at 808-586-2790 or the Hawaii Civil Rights Commission at 808-586-8636. Additional information about GINA is available at the end of this consent form.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and University of Hawaii Cancer Center staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom University of Hawaii Cancer Center sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the Principal Investigator, Charles J. Rosser, M.D., M.B.A., F.A.C.S. at 808-564-5994, who will let the researchers know. Then, any sample that remains in the bank will no longer be used. Samples or related information that have already been given to or used by researchers will not be returned.

If you decide to withdraw your specimens from the University of Hawaii Cancer Center **Specimen Repository in the future, a written withdrawal of consent should be submitted through your study doctor to the Principal Investigator, Dr. Charles Rosser at University of Hawai'i Cancer Center, 701 Ilalo St., Rm. 327, Honolulu, HI 96813. Please designate, in the written withdrawal, whether you would prefer to have the specimens destroyed or returned to the study doctor.**

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the Principal Investigator, Charles J. Rosser, M.D., M.B.A., F.A.C.S. at 808-564-5994.

Please **circle** your answer to show whether or not you would like to take part in each option:

SAMPLES FOR FUTURE RESEARCH STUDIES:

My samples and related information may be kept in a Biobank for use if future health research.

YES NO

(Please circle your choice)

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AS MODIFIED
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FUTURE CONTACT

I agree to be contacted by the University of Hawaii Cancer Center in the future regarding my participation in this study

_____YES _____NO

(Please **initial** your choice)

SIGNATURES

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study *and any additional studies where I circled 'yes'.*

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

	Subject's Name – PRINTED
Date	Signature of Subject
	Name of Person Conducting Informed Consent - PRINTED
Date	Signature of Person Conducting Informed Consent

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SPECIMEN CONSENT SUPPLEMENTAL SHEETS

HOW ARE SPECIMENS USED FOR RESEARCH?

WHERE DO SPECIMENS COME FROM?

A specimen may be from a blood sample or from bone marrow, skin, toenails or other body materials. People who are trained to handle specimens and protect donors' rights make sure that the highest standards of quality control are followed by University of Hawaii Cancer Center. Your doctor may not work for University of Hawaii Cancer Center, but has agreed to help collect specimens from many patients. Many doctors across the country are helping in the same way.

WHY DO PEOPLE DO RESEARCH WITH SPECIMENS?

Research with specimens can help to find out more about what causes cancer, how to prevent it, how to treat it, and how to cure it. Research using specimens can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

WHAT TYPE OF RESEARCH WILL BE DONE WITH MY SPECIMEN?

Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen may look for genetic causes and signs of disease.

HOW DO RESEARCHERS GET THE SPECIMEN?

Researchers from universities, hospitals, and other health organizations conduct research using specimens. They contact the University of Hawai'i Cancer Center and request samples for their studies. The University of Hawai'i Cancer Center reviews the way that these studies will be done, and decides if any of the samples can be used. The University of Hawai'i Cancer Center gets the specimen and information about you from your hospital, and sends the specimen samples and some information about you to the researcher. The University of Hawai'i Cancer Center will not send your name, address, phone number, social security number or any other identifying information to the researcher.

WILL I FIND OUT THE RESULTS OF THE RESEARCH USING MY SPECIMEN?

You will not receive the results of research done with your specimen. This is because research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future.

WHY DO YOU NEED INFORMATION FROM MY HEALTH RECORDS?

In order to do research with your specimen, researchers may need to know some things about you. (For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked?) This helps researchers answer questions about diseases. The information that will be given to the researcher may include your age, sex, race, diagnosis, treatments and family history. This information is collected by your hospital from your health record and sent to the University of Hawaii Cancer Center. If more information is needed, the University of Hawaii Cancer Center will send it to the researcher.

WILL MY NAME BE ATTACHED TO THE RECORDS THAT ARE GIVEN TO THE RESEARCHER?

No. Your name, address, phone number and anything else that could identify you will be removed before they go to the researcher. The researcher will not know who you are.

HOW COULD THE RECORDS BE USED IN WAYS THAT MIGHT BE HARMFUL TO ME?

Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). The results of genetic research may not apply only to you, but to your family members too. For disease caused by gene changes, the information in one person's health record could be used against family members.

HOW AM I PROTECTED?

The University of Hawaii Cancer Center is in charge of making sure that information about you is kept private. The University of Hawaii Cancer Center will take careful steps to prevent misuse of records. Your name, address, phone number and any other identifying information will be taken off anything associated with your specimen before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person which will help to protect your privacy.

WHAT IF I HAVE MORE QUESTIONS?

If you have any questions, please talk to your doctor or nurse, or call the Western Institutional Review Board® (WIRB®) at 1-800-562-4789.

11/09/15
01/11/16-V2
05/16/16-V3
10/12/16-V4
02/07/17-V5

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THE GENETIC INFORMATION NONDISCRIMINATION ACT

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that prohibits discrimination in health coverage and employment based on genetic information. This Federal law generally 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:

- Health insurance companies and group health plans may not request your genetic information that is obtained from research.
- Health insurance companies or health plan administrators engaged in research may not use the information obtained to discriminate against you.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information from research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Limitations (The following are not all inclusive, but the main limitations of GINA):

- The law does not exclude life insurance companies from using genetic information to make decisions.
- The law does not protect an individual if they already have a disease. It only protects an individual that has a genetic predisposition to a disease.

For more detailed information regarding the provisions of GINA see:

http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf