Combined Consent and Authorization to Participate in a Research Study

TITLE OF STUDY: 13-HN-23-MCC: A Pilot study of Concentrated Beet Root in participants being treated for locally advanced, previously untreated squamous cell cancer of the head and neck: A University of Kentucky Markey Cancer Center Trial

INVESTIGATOR INFORMATION: **D. Travis Thomas, PhD, RD**
University of Kentucky
Department of Health Sciences
Weekdays: (859) 218-0863 or (859) 257-3379
Evenings & Weekends: (859) 323-5321, ask Operator to page Radiation Oncologist On-call

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about dietary nitrate/nitrite supplementation and the effect on treatment compliance of radiation and/or chemotherapy. You are being invited to take part in this research study because you have been diagnosed with squamous cell cancer of the head and neck, and are planned for radiation and/or chemotherapy treatment. If you volunteer to take part in this study, you will be one of about 35 people to do so at the University of Kentucky.

WHO IS DOING THE STUDY?
The person in charge of this study is Travis Thomas, PhD, RD of the University of Kentucky, Department of Clinical Sciences. He is being assisted by Mahesh Kudrimoti, MD of the Department of Radiation Medicine, Jody Clasey, PhD, FACSM of the Department of Kinesiology and Health Promotion, and Emily Van Meter, PhD of the Department of Biostatistics of the University of Kentucky. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

By doing this study, we hope to determine if, dietary nitrate/nitrite supplementation improves compliance of medical treatment for head and neck cancer patients, prevents loss of muscle mass and strength, and reduces impact of negative side effects due to treatment compared to patients who choose not to receive dietary nitrate/nitrite supplementation.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not take part in this study if you are under the age of 18, pregnant, not willing to use adequate birth control methods before, during and four months after the study, participating in another study,or HIV-positive.

You should not participate in the beetroot group if you are allergic to beetroot, or not able to consume beetroot juice.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

For both beetroot and standard of care volunteer groups, the research procedures will be conducted at the University of Kentucky in the Markey Cancer Center, Center for Clinical and Translational Science, and Multidisciplinary Science Building. If you agree to participate in the study, you will be asked to come to the Markey Cancer Center, Center for Clinical and Translational Science and Multidisciplinary Science Building a total of three times for study tests. Overall, you will be a part of the study for 12-16 weeks and undergo study tests on three days throughout this period.

WHAT WILL YOU BE ASKED TO DO?

All Patient Volunteers
As part of a scheduled medical visit 1-2 weeks before you begin your scheduled treatment, you will be asked to come in to complete your study tests (baseline). On the last day of your therapy, you will be asked to complete the second set of study tests (midpoint). Most of the same tests that were performed 1-2 weeks before the beginning of treatment will be done again. On the day of your scheduled medical follow-up visit, you will return to the Markey Cancer Center, Center for Clinical and Translation Science and Multidisciplinary Science Building to undergo the third and last day of study tests (endpoint). These will be most of the same tests as those you completed on the first and second study test dates. On the three test days, most of the tests will be done following one another and will take between 2-4 hours total.

Beetroot Patient Volunteers Only
Between the completion of the first date of study tests and the beginning of your treatment (described above) you will be asked to consume a liquid beetroot supplement in the afternoon of each day during the week (Monday through Friday). During your 7-8 week therapy period you will be asked to continue taking the supplement in the afternoon of each weekday (Monday-Friday). On testing days, you will be asked to not consume the supplement before treatment because it will be given to you after treatment and before the blood draw. Beginning on the first date of study tests, you will be asked to consume the supplement in the afternoon of each weekday (Monday-Friday) throughout the entire 12-16 weeks, except on test days, until you have completed the study. After finishing the study tests on this day, your participation in the study will be completed.

Beginning on the first date of study tests, you will be asked to consume a liquid beetroot supplement in the afternoon (12-5pm) of each weekday (Monday-Friday) throughout the entire 12-16 weeks until you have completed the study. On scheduled testing days you will be asked to not consume the supplement because it will be given to you after treatment and before the blood draw.. You will be shown how to mix and administer the supplement and how to record consumption on your supplement log by the study staff on the first study test day after radiation treatment. After that, you will mix and consume on your own. An instruction sheet that includes steps on mixing, administering and recording the supplement and a supplement log will be given to you. The supplement will be provided in weekly supplies. Throughout the study, you will receive weekly phone calls from research staff encouraging you to continue taking your supplement.

The three testing dates will occur in conjunction with your medical treatment visits. Study assessments will include a medical history, physical examination, pregnancy test, blood pressure and heart rate measurement, blood draw and saliva sample, oral health and chemotherapy toxicity assessment, Computed Tomography (CT) scan, bone density scan (Dual Energy X-Ray Absorptiometry), Quality of Life survey, and muscle strength and endurance tests. For these three scheduled testing days, the supplement will be consumed at the testing area.

The first study test date will include a medical history, physical examination, pregnancy test, blood pressure and heart rate measurement, blood draw and saliva sample, oral health and chemotherapy toxicity assessment, Computed Tomography (CT) scan, bone density scan (Dual Energy X-Ray Absorptiometry), Quality of Life survey, and muscle strength and endurance tests. The supplement will be consumed on this day at the testing area. On the second study test date, you will complete the same tests except for the pregnancy test. You will consume the supplement on this day at the testing area. On the final (third) test date you will undergo the same tests as the second day.

What Beetroot Patients will be asked to do during each testing period:

- Baseline (1-2 weeks before treatment begins): medical history, physical examination, pregnancy test, blood pressure and heart rate measurement, blood draw and saliva sample, oral health and therapy assessment, Computed Tomography (CT) scan, bone density scan (Dual Energy X-Ray Absorptiometry), Quality of Life survey, and muscle strength and endurance tests.
- During the 1-2 weeks before treatment: supplement will be taken in the afternoon of each weekday (Monday-Friday)
- During the 7-8 week treatment: supplement will be taken in the afternoon of each weekday (Monday-Friday), weekly therapy and oral health assessments

- Midpoint (last day of treatment): medical history, physical examination, blood pressure and heart rate measurement, blood draw and saliva sample, oral health and therapy assessment, taking of supplement, CT scan, bone density scan, Quality of Life survey, and muscle strength and endurance tests
- During the 4-6 weeks after treatment completion and before follow-up visit: supplement will be taken in the afternoon of each weekday (Monday-Friday)
- Endpoint (4-6 weeks after treatment completion; final test day): medical history, physical examination, blood pressure and heart rate measurement, blood draw and saliva sample, oral health and therapy assessment, taking of supplement, CT scan, bone density scan, Quality of Life survey, and muscle strength and endurance tests

On testing days (baseline, midpoint, and endpoint) most of the tests/measures will be done in a particular order. The tests that may not follow a certain order during each testing day include: CT scan, medical history, physical examination, pregnancy test, blood pressure and heart rate measurement, and oral health and therapy toxicity measures. The CT scan may not be completed on the testing day due to a scheduling conflict, but will be within 7 days of the testing date. If the CT scan is done on the test day, you will be transported to the ground level of the MCC to perform the CT scan. The scan will last around 15 minutes. Following the CT scan, the Quality of Life survey and bone density scan will be completed in the CCTS. This survey and scan will take approximately 20 minutes to complete. Then you will be asked to consume your supplement.

Approximately 20-25 minutes after the supplement is consumed, you will be asked to complete a blood draw and saliva sample. This should take about 10 minutes. You will then be transported to the MDS for the lower and upper body muscle strength and endurance tests. These tests will last around 45 minutes. Once this is finished, you will be done with study testing and treatment for the day. Overall, this will take approximately 2-3 hours.

Questions about what your diet the previous day will be completed as part of the nutritional status assessment. However, these will not be done on testing days. They will be completed by a nutrition graduate student within 2 weeks of the baseline and midpoint testing days. This will be done a total of four times.

Patient Volunteers Not on Beetroot
You will be asked to follow the same testing schedule as described above, without consuming the beetroot supplement. Additionally, you will not be asked about your diet.

You will be asked to perform the following:

Standard Care:

1. Radiation and/ or Chemotherapy (IMRT)
This is the treatment prescribed to you by your physician. All of this treatment is considered standard care. Any changes in treatment will be made by your treating physician. This includes the radiation and/or chemotherapy, and any medications that are prescribed as part of treatment.

2. Therapy and Oral Health Assessment
You will be asked to complete weekly assessments of the effect of your treatment on both your function and oral health by your radiation oncologist. It will be done separate from your study tests.

3. Pregnancy Tests
As part of the standard care routine, female patients will be asked to perform pregnancy tests throughout the 7-8 week treatment period.

4. Routine Medical Examination
As part of routine visits for treatment and scheduled medical appointments, you will be asked to complete routine measurements (heart rate, blood pressure, physical examination) and provide your medical history.

Research Tests and Procedures:

All Volunteers

1. Computed Tomography Scan (CT)

You will be asked to undergo a CT scan. This scan will measure the muscle and fat in your thighs and forearms. You will be asked to lie flat on your back on the CT scan area. While CT scans are a part of your standard treatment, the scans to measure thigh and forearm muscle and fat are not standard care.

2. Blood Draw and Saliva Sample

You will be asked to give a blood sample and saliva sample on the 3 study test days. Approximately 8mL, 1.5 teaspoons, of blood will be drawn from your arm vein to determine plasma nitrate/nitrite and vitamin D for future assessment. You will be asked to spit into a tube for a few minutes until there is an adequate amount of saliva. This will be later assessed to determine saliva nitrite.

3. Bone Density Scan: Total Body Dual Energy X-ray Absorptiometry (DXA)

You will be asked to take part in a bone density (DXA) scan. You will be asked to remove all objects such as jewelry and eyeglasses and wear only a hospital gown or t-shirt and shorts containing no metal during the procedure. This scan will be used to determine bone density, muscle and fat mass. During the scan you will lie flat on your back.

4. Hand-Grip Strength and Endurance Test

You will be asked to use a handgrip dynamometer, which will be used to determine handgrip strength and endurance in both arms. You will be in a standing position, arms at your side not touching your body, and elbow bent slightly. You will be asked to squeeze the dynamometer, similar to squeezing a handle, as hard as possible and hold for about 90 seconds. You will squeeze the dynamometer multiple times with rest between each squeeze. This test may be repeated if the test results vary too much. This repeat will take place after a rest period.

5. Lower Body Strength and Endurance Test

You will be asked to use a Biodex machine to complete a one-legged maximum strength test to measure fatigue and endurance of your muscle. You will be instructed on proper lifting and breathing techniques before the test. You will be in a seated position on the Biodex and you will be strapped around the shoulders and waist to stabilize you and minimize the use of other muscles. The test will be done using your dominant leg and you will be asked to kick with maximum effort. Before you start the test, you will perform warm-up kicks at a moderate intensity with a rest period between each. Then the maximal strength test will be completed with a rest period between each kick. You will be instructed to use maximal effort in each of the kicks for the recording test. For the endurance test you will be asked to complete approximately 25 kicks at a fast pace followed by another strength trial of maximum effort kicks.

6. Quality of Life

You will be asked to complete a question and answer survey that is used to determine your quality of life.

7. Pregnancy Testing and Birth Control Methods

Female patients will be asked to complete a pregnancy test during the first (baseline) study test day. This will be the only pregnancy test done for study purposes. For study purposes, all patients will be asked to use adequate contraception (hormonal or abstinence) before, during and/or after the study period. Women will be asked to use contraception before and during the entire study. Men will be asked to use contraception before, during and 4 months after completion of the study. The effects of beet root on the developing human fetus are unknown and chemoradiation has the potential for harmful effects.

Beetroot Patient Volunteers Only

1. Supplement Administration

You will be asked to mix 10g of beetroot supplement powder with 4-8 oz. of water and drink in the afternoon (12pm-5pm) of each day during the week (Monday-Friday). You will be shown how to mix the supplement by research staff on the first study test day so that you may drink or administer the supplement without

help. A hand copy of instructions on mixing, drinking/administering and recording the supplement will be given to you as well. After this time, you will be asked to complete this on your own. If at any point you begin tube-feeding during the study, you will be taught how to self-administer the supplement at that time by research staff. If at any point you are unable to mix and administer your supplement yourself and wish to continue with the study you may ask for assistance from the MCC staff. The staff may help you or identify a family member that will be taught to assist in mixing and administration. You will be asked to start consuming the supplement on the first day of study measures and will stop when you are finished with the study. You will be asked to record the day, time and amount of the supplement consumed on a supplement log. This will be given to you when you receive the supplement. The supplement will be given to you during scheduled medical visits throughout the entire study time period.

Supplement logs will be provided to you as needed. You will be asked to keep all used and unused supplement packaging and return them to research staff. You will be asked to return the logs and supplement packaging each time your supplement supply is given to you.

2. Diet and Nutritional Assessment

For only patients receiving beetroot, four dietary recalls will be conducted throughout the study to assess diet and nutrition. Two recalls will occur twice within a two weeks period surrounding the first two testing dates. For the recall you will be asked what you ate and drank the day before the recall. A trained nutrition graduate student will complete each recall.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You have been told that the study may involve the following risks and/or discomforts.

For All Patient Volunteers

Blood Draw

While inserting the needle into the vein to draw blood, there may be some slight discomfort experienced. Also, with needle insertion, potential infection, soreness, pain, bleeding, bruising, and fainting may occur.

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Soreness	It occasionally occurs	Can be easily treated	Yes
Pain	It occasionally occurs	Does not impact your overall health	It will go away within 24 hrs
Bleeding	It occasionally occurs	Can be easily treated	Yes, by applying pressure
Bruising	It occasionally occurs	Can be easily treated	Yes
Fainting	It is uncommon	Can be easily treated by lying down with legs elevated	Yes, usually in 20 minutes
Infection	It is very uncommon	Can be treated	Yes

Bone Density (DXA) Scan

The radiation dose from a typical DXA bone density scan produces approximately 1/300th of the natural background radiation dose we receive each year. This radiation dose would not be considered a risk of producing any harmful effects.

Lower Body Strength and Endurance Test
Muscle strength testing may be associated with some risk. The risks include muscle tightness, soreness, fatigue, and could possibly cause a strained muscle. However, these symptoms are no different than what would normally result as a part of any strength testing or exercise. These symptoms are temporary and recoverable. The cardiovascular risk of performing these exercises and tests are very low but include abnormal pressure and fainting, cardiac arrhythmia and death. For those individuals with low bone density, strength testing may also result in bone injury such as bone fractures.

CT scan
Each CT scan will give a radiation dose greater than that from typical natural background exposure, but less than the limit for radiation workers and well below the levels that are considered to be a significant risk of any harmful effects.

There is always a chance that any medical treatment can harm you, and the investigational treatment in this study is no different. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

Beetroot patient volunteers only

Beetroot Juice
Potential side effects of consumption are rare and include: stomach cramping/diarrhea, pink colored urine and stools, and allergic reactions.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

For all volunteers, there is no guarantee that you will get any benefit from taking part in this study.

However, for Beetroot juice volunteers, many studies suggest that beetroot improves endurance and strength during exercise, and lower blood pressure. Your willingness to take part, however, may, in the future, help doctors better understand and/or treat others who have your condition.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, there are other choices such as participating in a different research study or not participating in a research study

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you receive during this study that you would normally receive for your condition. These are costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare or Medicaid for the medical procedures done strictly for research. Therefore, these costs will be paid by the University of Kentucky.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you to the extent allowed by the law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. Collection of Social Security Number, address and full name will be necessary so that the University can fulfill any federal income tax reporting requirements and for the research team to process your compensation. If you choose to withhold this information you may still participate without compensation. If you choose to participate in the study, every effort will be made to keep all personal information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. You will be randomized and assigned a sequence number at the start of the study through the OnCore data system. This number will be used to separate identity from health information used in the study. Cancer treatment data, adverse events, compliance with beetroot supplement, strength and endurance measures, and Quality of Life surveys will be collected and managed using the MCC online research center, OnCore. All physical records will be kept in locked files in research offices that only our research personnel have access.

You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else.
Officials of the National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), NeoGenis® Labs, and the University of Kentucky may look at and copy pertinent portions of records that identify you.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study. Your future medical treatment and relationship with the treating physician will not be affected.
The individuals conducting the study may need to withdraw you from the study, and the study will no longer be provided by the investigator. This may occur if you are not able to follow directions that are given to you, if they find your being in the study is more risk than benefit to you, if you decide you want to change from one study group to another, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or get sick because of something that is due to the study, you should call Mahesh Kudrimoti, MD at 859-323-0283. Dr. Kudrimoti will determine what type of treatment, if any, that is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research or related harm may be paid by your insurer if you are insured by a health insurance company or by Medicare or Medicaid if you are covered by either, and if not, then it will be your responsibility to pay the medical costs.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will have the potential to receive a total of $90. This will be prorated based on completion of certain time points in the study. If you complete the study through the midpoint testing day, you will receive $60. If you complete the study through the endpoint testing day, you will receive an additional $30. If you earn $600 or more by participating in any research, it is potentially reportable for tax purposes.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Travis Thomas, at 859-218-0863. You may also contact your Research Coordinator at 859-323-2042. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

CHOICE OF PARTICIPATING WITH OR WITHOUT BEETROOT

If interested in participating in this study, please indicate which research group you would like to be assigned to:

☐ Beetroot ☐ No Beetroot _____Initials

POTENTIAL FUTURE USE

Blood and Saliva Specimen

Travis Thomas, PhD, would like to keep some of the blood and saliva collected during the main study participation but is not used for other tests for that study. No additional blood or saliva will be taken. If you agree, the blood and saliva samples may be used in future testing.
Researcher may also need health information about the people who provide specimens. We are also asking your consent to place information from your medical record and/or research record in a database to be used for research. Your name and address will not be placed in the database.

Please read each sentence below and think about your choice. After reading each sentence, mark “yes” or “no”. If you have questions, please talk to the investigator or staff. Remember, no matter what you decide to do about the storage, or banking, and future use of your blood and saliva samples, you may still take part in the main study. If you answer yes to either choice below you also give your authorization for your accompanying health information to be used and disclosed along with the blood.

1. Do you give permission for your blood and saliva to be kept by Dr. Thomas in a central location/specimen bank at the CCTS laboratory until they are used up but no longer than 5 years for use in future research to learn more about how to prevent, detect or treat squamous cell carcinoma of the head and neck?

   ☐ Yes ☐ No _____Initials

2. Do you give permission for your blood and saliva samples to be used for future research about other health problems?

   ☐ Yes ☐ No _____Initials

The sample(s) (blood and saliva) you are giving will no longer belong to you and might be used in studies that lead to new products for research, diagnosis or treatment. These products might have some commercial value. There are no plans to provide financial compensation to you should this occur.

Genetics research and banking:

In addition to the main study, you are being asked to volunteer in a genetic sub-study to study your genes, or DNA (deoxyribonucleic acid). Genes are made up of DNA. Your DNA is like a huge database of chemical bases that carry the "blue prints" or instructions to tell each and every cell in your body what they should do. Genes can influence the likelihood that you will get certain diseases. Your participation in this sub-study is optional. You can still be in the main study even if you do not wish to participate in this sub-study.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), 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 we get from this research.
- 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 that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Please read each sentence below and think about your choice. After reading each sentence, mark "yes" or "no." If you have questions, please talk to the investigator or staff. Remember, no matter what you decide to do about the storage, or banking, and future use of your DNA samples, you may still take part in the main study.

You give your permission for your DNA to be stored in a central location/DNA bank at the CCTS laboratory for future use by the study investigators. We plan to store (or bank) the DNA samples until they are used up but they will not be kept longer than 5 years. You give authorization for your accompanying health information to be used and disclosed as marked below:

1. Do you give permission for your DNA samples to be kept by Dr. Thomas for use in future research to learn more about how to prevent, detect, or treat squamous cell cancer?

   ☐ Yes ☐ No _____Initials

2. Do you give permission for your DNA samples to be used for future research about other health problems?

   ☐ Yes ☐ No _____Initials

Contacting Research Subjects for Future Studies

Do you give your permission to be contacted in the future by Dr. Thomas regarding your willingness to participate in future research studies about how to prevent, detect or treat squamous cell cancer of the head and neck?

☐ Yes ☐ No _____Initials

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data/blood obtained from you may be shared with other investigators in the future. If that is the case the data/blood will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

NeoGenis® Labs is providing material for this study.

A description of this clinical trial will be available on http://www.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.

AUTHORZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researcher to protect your health information. The following sections of the form describe how researcher may use your health information.

Your health information that may be accessed, used and/or released includes:

- Diet and nutritional status (beetroot volunteers only)
- Muscle strength and endurance
- Bone Density scan (DXA) results
- Treatment compliance and results
- Therapy and oral health measures
- CT scan results
- Routine physical examination results
- Medical history
- Quality of Life survey

The researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law Enforcement Agencies when required by law.
- University of Kentucky representatives.
- UK Hospital.
- Investigational Drug Service
- National Cancer Institute (NCI)
- Food and Drug Administration (FDA)
- Center for Clinical and Translational Sciences
- NeoGenis® Labs and Sport

- Dr. Nathan Bryan

The researchers agree only to share your health information with the people listed in this document.
Should your health information be released to anyone that is not regulated by privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.
You will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**
- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans**
- **Eligibility for benefits**

After signing the form you can change your mind and NOT let the researcher(s) release or use your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Dr. Travis Thomas, 209H Charles T. Wethington Building, 900 S. Limestone, Lexington, KY 40536 to inform him of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You may not be allowed to participate in the study.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer at: (859) 323-1184.

You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

_____ _____
Signature of research subject or *research subject's legal representative — Date

_____ _____
Printed name of research subject or *research subject's legal representative — Representative's relationship to research subject

**(If, applicable)* Please explain Representative's relationship to subject and include a description of Representative's authority to act on behalf of subject:

_____
_____

_____
Name of [authorized] person obtaining informed consent/HIPAA authorization Date

_____
Signature of Investigator