Safety, Feasibility and Efficacy of Sulforaphane (Avmacol Extra Strength) in Chronic Kidney Disease – Randomized, Double-blind, Placebo-controlled Trial

NCT05797506

Consent

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Department of Medicine
Nephrology Division

UNIVERSITY of ROCHESTER MEDICAL CENTER

CONSENT FORM

HEROES Study

Health **E**ffects (**R**enal) **O**f **E**xtra **S**trength Avmacol

Safety, Feasibility and Efficacy of Sulforaphane (Avmacol Extra Strength) in Chronic Kidney Disease: Phase II – Randomized, Double-blind, Placebo-controlled Trial

Principal Investigator: Thu H. Le, MD
Chief, Division of Nephrology

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you have been clinically diagnosed with Chronic Kidney Disease (CKD).
- The purpose of this study is to determine the safety, and efficacy of the study drug, Avmacol Extra Strength (ES) tablets in patients with CKD.
- Avmacol ES tablets are commercially available over the counter however, it has never been tested in patients with kidney disease. Avmacol ES tablets have not been approved by the Food and Drug Administration (FDA) for treatment of chronic kidney disease and is therefore investigational for the purpose of this study.
- You will be randomized (like the flip of a coin) to Avmacol ES tablets or placebo tablets. The placebo tablets will look like the study drug, but they contain no active ingredients. Neither you nor the study team will know which tablets you are taking. If there is an adverse event, the study team will be able to find out quickly what group you were assigned to. You will take 2 tablets once daily for the first week and then 4 tablets once daily.
- You will receive $25.00 for each completed in-person visit, up to a total of $100.00.
- Your participation in this study will last 6 months. It will be less if you develop serious side effects or have side effects to Avmacol ES tablets that cannot be helped by reducing the dose.
- Study procedures will include a cheek swab to extract DNA, three phone calls, monthly health questionnaires, study visits at Strong Memorial Hospital (SMH) for blood pressure (BP) check and blood and urine collection. For your convenience, this visit could be held after your

routine clinic visit.

- There are risks from participating.
  - The most common risks with Avmacol ES tablets are side effects of headache, nausea and indigestion, which are lessened or prevented when taken with food.
  - The most serious risk with Avmacol ES tablets is the possibility of allergic reaction. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You might not benefit from being in this research study. The potential benefit to you might be improvement in inflammation and decreased kidney disease progression rate.
- Information from your medical record will be obtained for the study.

Purpose of Study

The purpose of this study is to test the safety of Avmacol ES tablets to determine if it can decrease kidney disease progression rate, decrease markers of oxidative stress, and inflammation that is usually high in patients with kidney disease.
If proven to be safe and well tolerated over 6 months, this study will help determine whether a much larger study with much longer duration (5 years) should be conducted with the aim of slowing down kidney disease progression.

Description of Study Procedures

If you agree to participate, your participation in the study will be for 6 months.
Medical Record Data: A member of the study team will access your medical record to collect information about your age, sex, race, height and weight, medications you are taking, and the results of any laboratory or diagnostic tests to ensure that you are eligible for the study.

Buccal (cheek) swab:

- After you consent to participate in the study, a buccal (cheek) swab will be obtained to extract DNA – only to determine if you have or don't have the GSTM1 gene that can impact the way Avmacol ES tablets are metabolized. Up to 50 percent of human populations do not express this gene.
- We will only determine whether you have the GSTM1 gene that may influence your response to Avmacol ES tablets. We will not look at any other gene and no other genetic testing will be done on your DNA sample.
- The result of the GSTM1 gene test will NOT be recorded in your medical record.
- We will store your DNA sample for 5 years unless we receive your request for us to discard your sample sooner. Your request can be by simple phone call, in person, or by email to our study team.

Blood draw: You will have a small blood draw of about ~20 mL (4 teaspoons) at each in-person study visit.

Urine collection: You will be asked to provide a urine sample at each in-person study visit.

Pregnancy test: If you are of childbearing potential, a pregnancy test will be performed on the urine sample you provide at each in-person visit unless you

1. Have had a hysterectomy OR
2. Are above 50 years of age and your last menstrual cycle was over two years ago.

Questionnaires: You will be asked to complete 3 questionnaires monthly to monitor your health. The questionnaires will be completed in-person during the study visits at months 0, 1, 3, and 6. For the phone call visits at month 2, 4, and 5, you will be given the option to answer the digitally questionnaires using a link that will be emailed to you or over the phone.

- *General Questionnaire:* Includes questions about how you are feeling, if you experience any new symptoms, and your intake of cruciferous vegetables.
- *Gastrointestinal Questionnaire:* Includes questions about symptoms.
- *Kansas City Cardiomyopathy Questionnaire:* Includes questions about heart failure symptoms.

Dosing: You will be randomized (like the flip of a coin) to take the study drug, Avmacol ES tablets or placebo tablets once daily for 6 months. For the first week, you will be asked to take two (2) tablets once daily and then four (4) tablets once daily for the remaining study period.

At Home Procedures: At the month 0 visit, you will be given a 3-month supply of tablets (plus enough to last 2 extra weeks).

- For the first week, you will be asked to take 2 tablets once daily and then 4 tablets once daily for a total of 6 months. You will be asked to take the tablets after a meal.
- You will be asked to avoid hot drinks such as coffee, tea, etc. for an hour before taking the tablets and an hour afterwards.
- A reusable medication tracker called Take-n-slide and calendar will be provided to you to track the days you take the tablets. The Take-n-slide is yours to keep after the study.

Long-Term Follow Up: To determine the long-term effects of Avmacol ES tablets, we will continue to collect data from your electronic health record including your blood pressure and results of lab testing. If you agree, this will continue for 5 years. You will be given the option at the end of the consent to decide if you want to participate in long term follow up.

What to expect at each study visit- For your convenience, the study coordinators will aim to schedule your study visits on the same day as your routine visits to the clinic. To save you an extra visit to the lab for this study, we will ask that you get your routine SOC lab tests (blood, urine) done at SMH, so we could collect blood and urine for the study at the same time.

Month 0: This visit may occur at Strong Memorial Hospital's Kidney Clinic (AC3) or Highland Hospital. The following procedures will occur at this visit:

1. Review the consent form and if you choose to participate, sign it.

2. BP check, blood and urine collection at Strong Memorial Hospital (Highland Hospital patients will be asked to travel to Strong Memorial Hospital and given a parking/bus pass).
3. Pregnancy test by the study coordinator if you are of childbearing potential.
4. Assignment to either arm of the study (Avmacol ES tablets or placebo tablets) and collection of 3-month supply of the tablets.
5. Health questionnaires.

Month 0.5: Two weeks after starting the tablets, you will have a phone call with the study coordinator to see how you are doing and if you are experiencing any side effects.

Month 1: You will be asked to bring the study calendar we gave you to track the days you took the tablets. The following procedures will occur at this visit:

1. BP check, blood and urine collection at Strong Memorial Hospital.
2. Pregnancy test by the study coordinator if you are of childbearing potential.
3. Health questionnaires and a 5-question survey about the take-n-slide medication tracker

Month 2: You will have a phone call with the study coordinator to discuss your health. You will also be asked to answer the three health questionnaires either through a link that will be emailed to you OR over the phone.

Month 3: You will be asked to bring the study calendar we gave you to track the days you took the tablets. The following procedures will occur at this visit:

1. BP check, blood and urine collection at Strong Memorial Hospital.
2. Pregnancy test by the study coordinator if you are of childbearing potential.
3. Health questionnaires.

Month 4: You will have a phone call with the study coordinator to discuss your health. You will also be asked to answer the three health questionnaires either through a link that will be emailed to you OR over the phone.

Month 5: You will have a phone call with the study coordinator to discuss your health. You will also be asked to answer the three health questionnaires either through a link that will be emailed to you OR over the phone.

Month 6: You will be asked to bring the study calendar we gave you to track the days you took the tablets. The following procedures will occur at this visit:

1. BP check, blood and urine collection at Strong Memorial Hospital.
2. Pregnancy test by the study coordinator if you are of childbearing potential.
3. Health questionnaires.

Relevant information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

Schedule of Assessments:

Study visits	What to bring with you	What to expect	Samples to provide & Location at Strong Memorial Hospital (SMH)
Routine clinic visit/Baseline Month 0: Date lab samples are drawn		• Informed consent • Buccal (cheek) swab • Pregnancy test • **Receive 3-month supply of tablets** • Reusable medication tracker Take-n-slide and calendar	• Buccal swab, BP check at Strong Hospital's Kidney Clinic (AC3) or Highland Hospital • Blood, Urine – Strong Hospital's Outpatient Labs
Month 0		• *Wellness check*	*None*
Month 1	• Calendar to track tablet intake	• Questionnaires • Review of tablet intake • Pregnancy test • Survey on Take-n-slide	• BP check at Strong Hospital's Kidney Clinic (AC3) • Blood, Urine – Strong Hospital's Outpatient Labs
Month 2		• *Questionnaires* • *Review of tablet intake*	*None*
Month 3	• **Bottles of the tablets** • **ALL remaining tablets** • Calendar to track tablet intake	• Questionnaires • Review of tablet intake • Pregnancy test • **Receive 3-month supply of tablets**	• BP check at Strong Hospital's Kidney Clinic (AC3) • Blood, Urine – Strong Hospital's Outpatient Labs
Month 4		• *Questionnaires* • *Review of tablet intake*	*None*
Month 5		• *Questionnaires* • *Review of tablet intake*	*None*
Month 6	• **Bottles of the tablets** • **ALL remaining tablets** • Calendar to track tablet intake	• Questionnaires • Review of tablet intake • Pregnancy test	• BP check at Strong Hospital's Kidney Clinic (AC3) • Blood, Urine – Strong Hospital's Outpatient Labs

If you get the lab tests (blood, urine) that are part of your routine Standard of Care (SOC) done at a non-SMH location, this data will be collected from eRecord. In that case, we will ask that you provide a separate urine and blood sample at SMH for the biomarker lab tests (see page 9).

Future Use of Information/Samples

Your information and samples might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your information and samples are used or distributed. You will be given the option at the end of this consent form to decide if you would like your information or samples used for future research.

eRecord, MyChart, and your participation in this study

The following individuals may know you participated in research and may see study testing and results for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

The research team may be notified if you receive other health care services at URMC or any of its Affiliates (e.g., visit to the emergency room or urgent care).

If you have questions or concerns, you should discuss it with the research team.

Return of Research Results

Once the study is completed, we will send subjects a summary of the results and what they mean. In general, we will not give you any individual results from your participation in 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.

Some things you should know about the results:

- While we expect to have an idea how Avmacol ES tablets may impact markers of inflammation and oxidative stress in your body, it is possible the results will be difficult to interpret.
- For the genetic part of this study, we will only determine whether you have the GSTM1 gene that may influence your response to Avmacol ES tablets. We will not look at any other gene.

Risks of Participation

Avmacol ES tablets: While Avmacol tablets have been well-tolerated in other clinical trials such as for autism, chemotherapy drug toxicity, it has not been previously tested in patients with kidney disease. The potential risks are side effects of Avmacol ES tablets. The most common side effects are headache and gastrointestinal, including nausea and indigestion, which are lessened or prevented when taken with food. If you have a history of diarrhea, taking Avmacol may make

your symptoms worse. Since Avmacol tablets have a short half-life, we expect the side effects would be short-lived when you stop taking it.
Based on the multiple clinical trials that have been done with Avmacol tablets or the actual sulforaphane compound in other diseases, we do not anticipate any serious risks. Although not reported in any earlier trial, it is possible that you may have an allergic reaction to Avmacol ES tablets. This reaction may be mild, such as a skin rash, or you may have more severe symptoms like swelling of the throat, low blood pressure, and shortness of breath. In rare cases, a severe reaction could cause death.

Blood Draws: Blood draws may cause pain, redness, bruising or infection at the site of the needle stick. Rarely some people faint.

Buccal (cheek) Swab: The risk associated with this procedure are minimal.

Urine Sample: The risk is minimal. There is risk of spilling urine onto clothes during your collection.

Pregnancy: The effect of sulforaphane on the fetus is not known. If you think you may be pregnant, please immediately stop taking the tablets and notify the research team.

Risks of Questionnaires: There are no anticipated risks for you to complete the requested questionnaires other than the time it takes to complete them. If any questions make you uncomfortable, you may skip them or stop any time.

Risks to Social/Emotional Well-Being: We do not anticipate any psychological, social or legal risks beyond those related to participation in a clinical study.

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 website at any time. You can search this website for information related to this study by using this study's identification number NCT05797506.

Circumstances for Dismissal

You may be withdrawn from the study if you do not keep appointment for study visits or if you cannot complete study activities. Also, if you experience significant side effects that are not resolved by dose reduction. Lastly, you may be withdrawn from the study if your disease becomes worse or if your doctor or the investigator no longer feels participating in the research is in your best interests. if you become pregnant, or if you have a new diagnosis such as advanced heart failure, cardiovascular event, life threatening infection, or cancer.

Benefits of Participation

You might not benefit from being in this research study. The potential benefit to you might be improvement in inflammation and decreased kidney disease progression rate.

New Study Information
If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

Number of Subjects:
Approximately 100 subjects with chronic kidney disease will take part in this study.

Sponsor Support
The University of Rochester is receiving funding support from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) for conducting this research study.

Commercial Profit
We will use your information and/or samples for research only. However, the results of this research might someday lead to the widespread use of sulforaphane in the treatment of chronic kidney disease. You will not receive money from the sale of sulforaphane.

Compensation for Injury
If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The study investigator's name and phone number are listed in this consent form. The University of Rochester and the study investigator will determine whether your injury was the result of your participation in the study.

We will offer you the necessary care to treat your injuries. The costs of treatment may be billed to you or your insurer just like any other medical costs or covered by the University of Rochester or other third party, depending on several factors. If your insurance is billed, you may be responsible for deductibles and co-payments. There are no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If the care you receive as a result of your injury is paid for by the University of Rochester or another party, we will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

Costs
There will be no cost to you to participate in this study.

The Standard of Care (SOC) lab tests refer to Comprehensive metabolic panel (CMP), urinary albumin and protein/creatinine (PC) ratio when it is performed at a time-point recommended by your healthcare provider.
Billing: You and/or your insurance company will be responsible for the costs of these tests.

The Clinical Research lab tests refer to Comprehensive metabolic panel (CMP), urinary albumin and protein/creatinine (PC) ratio when it is performed at a time-point not recommended by your healthcare provider. These tests are for the research study only.
Billing: The research study will pay for all bills associated with these tests.

The Biomarker lab tests refer to plasma hydrogen sulfide, plasma and urine 8-isoprostane, urine nephrin, plasma interleukin-6. Also, mRNA levels of cytoprotective enzymes and heat shock proteins in peripheral blood mononuclear cells.
Billing: The research study will pay for any bills associated with these tests.

If you decide to have your SOC lab tests done at a non-SMH location, the study coordinators will collect this data from provider ordered SOC tests from EMR. In that case, you will need to come to SMH separately to provide a blood and urine sample for the ***Biomarker lab tests*** only and the research study will pay for it.

Payments
You will receive $25.00 for each completed study visit, up to a total of $100.00.

Month 0: $25.00

Month 1: $25.00

Month 3: $25.00

Month 6: $25.00
You will not be paid for visits that you do not complete. Expect up to 4-6 weeks for the payment to be processed and mailed after the completion of each study visit.

For this study we use a subject payment system called Advarra Participant Payments. The system allows three ways to provide payment. You can choose: a reloadable debit card; direct deposit; or mailed paper checks. The study team will help you create a "subject profile" in the system. In order to provide payment, you will need to enter your name and date of birth into your subject profile. Depending on which payment method you choose, you may also need to enter your email address and banking information. If you already have an Advarra account (because you are in another study that uses this system), your existing profile will be used to provide payment. See the 'Information Sheet for Advarra Participant Payments" for additional information.

Parking pass or bus pass:
You will be provided a parking pass for each study visit at the Strong Memorial Hospital, so you will not have to pay for parking. If you prefer, a bus pass will be provided instead. If you have significant mobility issues, you will be given an option to be reimbursed for valet parking service.
Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will not label your data/samples with identifying information about you,

such as your name, medical record number or social security number. We will label your data/samples with a unique ID# and store your identifying information linked to the code in a separate document. All data/samples will be stored in a secure manner.
If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- The investigator will have access to your personal and medical information
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- National Institute of Health (NIH) who is the sponsor for this study (they provide funding to conduct the study).
- Nutramax who provides Avmacol ES tablets and placebo tablets
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.
- University of Virginia
- Advarra Payment System

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, 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.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission. Once your information is disclosed to the named entities or organizations listed above, it is possible that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations.

Completion of the study
To ensure your safety after you have stopped taking the tablets, our research coordinator will call after about 2 weeks to ask how you are feeling, and whether you have developed any new symptoms.

Certificate of Confidentiality
To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Include the following only if applicable: The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Use of E-mail and/or Text Messaging in Research

You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. Text messages will be limited to scheduling and appointment reminders only.

Email and/or text communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the research team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email or texting. Email communications between you and the research team may be filed in your research record.

You are responsible for any fees charged by your carrier's service plan for text messaging. You may decide not to receive or send text messages with research study staff at any time, in person or by sending the research number a text message that says, "**Stop Text**". Your consent, and any request to stop email or text messaging, applies to this research study only.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Dr. Thu Le at 585-275-1554 or the nephrologist on call after regular hours.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. This will not affect the care you receive for chronic kidney disease.

CONSENT TO FUTURE USE OF INFORMATION / SAMPLES

Communication with the Study Team

YES *(initial)*	**NO** *(initial)*	*I consent to the use of **email** in this study. If yes, enter email address:* _____
YES *(initial)*	**NO** *(initial)*	*I consent to the use of **text messaging** in this study. If yes, enter phone number:* _____

Consent to Future Use and Re-Contact

YES *(initial)*	**NO** *(initial)*	*I consent for the study doctor, or someone from the study team, to contact me in the future about using my information for research that is not described in this consent form.*
YES *(initial)*	**NO** *(initial)*	*I consent for the study doctor, or someone from the study team, to contact me in the future about participating in future research studies.*

Consent for the Future Use of My Information and/or Samples

YES *(initial)*	**NO** *(initial)*	*I consent for the study doctor or someone from the study team to share my samples, GSTM1 data, health information with other researchers for future research not described in this consent. Only non-identifying demographics will be used.*

Consent to collect long-term follow up data

YES *(initial)*	NO *(initial)*	*I consent for the study doctor or someone from the study team to collect long-term follow up data.*

SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date