Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 2a Study Of Setipiprant Tablets In Androgenetic Alopecia In Males With A Comparator Arm

Informed Consent Form to Participate in Research

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INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have androgenetic alopecia (AGA) or male pattern baldness. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

Allergan plc (public limited company) is the sponsor of this study and the purpose of this research study is to investigate the safety,and efficacy of setipiprant tablets in the treatment of hair loss (also known as androgenetic alopecia (AGA) in males. The investigational study medicine is called (KYTH-105) Setipiprant tablets.

Setipiprant (KYTH-05) is an investigational drug. This means it has not been approved by the U.S. Food and Drug Administration (FDA). Drugs that do not have approval by the FDA cannot be sold or prescribed by your physician.

In this study Setipiprant (KYTH-05) will be compared to placebo and finasteride. A placebo is a substance, like a sugar pill, that is not thought to have any effect on your disease or condition. In this study you will either receive the active study medication, Setipiprant (KYTH-05) or placebo which is not active or finasteride. Placebos are used in research studies to see if the drug being studied really does have an effect. Finasteride has been approved by FDA for use in males only and is indicated for the treatment of male pattern hair loss.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 187 people at up to 20 research sites will take part in this study, including approximately 15 people at this research site.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin.

- Setipiprant tablets (KYTH-105)
- Placebo tablets (the medically inactive substance)
- Finasteride (active ingredient of Propecia®) 1 mg tablets

There is approximately 40% chance that you will be assigned to receive setipiprant, approximately 40% chance that you will be assigned to receive placebo, and approximately 20% chance that you will be assigned to receive finasteride.

The setipiprant tablets and placebo tablets will look exactly the same. Because of the type of study that you are participating in, neither you nor the study doctor or study staff will know whether you are taking setipiprant or placebo (a medically inactive substance that looks like study treatment, but does not contain the active substance) during the study. However, this information is available should the study doctor decide it is medically necessary.

The finasteride tablets will look differently from the setipiprant tablets and the placebo tablets. The finasteride tablets are included in this study for comparison of the results and confirmation in the sponsors efficacy measures. You and some of the study staff will know if you have been assigned to receive finasteride. Finasteride is the only FDA approved and marketed oral product for the treatment of male pattern hair loss in the US.

To keep the finasteride assignment unknown, a different study doctor will be completing the hair questionnaires for all subjects and will not know what treatment any subject has been given. This doctor will not be involved in any other procedures or aspects of the study. You should not show or discuss the appearance of the study drug, the packaging of the study drug, how often you take the study drug or anything related to the study drug with the study doctor who completes the hair questionnaires. You can ask the study staff who are allowed to know your treatment assignment any questions you might have about your study drug.

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

• The first visit is a *Screening Visit* to determine whether you meet the study entry criteria. The results from your screening tests are expected within 28 days.

• If you are eligible and agree to continue in the study, you will return for the *Baseline/Randomization Visit*, after which you will start taking the study drug.

• You will continue to take the study medication for approximately 24 weeks (6 months) and return to the clinic for 4 additional *Study Visits*, unless you and/or the study doctor decide you should stop taking it, for example, if you have a bad

side effect, you decide to withdraw from the study, your participation is stopped for any reason, or the study ends.

• After you stop taking the study drug, a final clinic visit will be scheduled approximately 8 weeks after your last dose.

• You may need to attend unscheduled visits for safety or other reasons.
The approximate duration of each visit in this study is described in the following table:

Type of Visit	Visit Schedule	Duration of Each Visit
Screening Visit	Approximately 28 days before Day 1	Approximately 3-4 hours
Baseline and Randomization	Day 1	Approximtely 2-3 hours
Study Visits	Weeks 4, 8, 16, and 24	Approximately 1-2 hours
End of Study Visit	Week 32	Approximately 1-2 hours

WHAT HAPPENS WHEN I COME IN FOR STUDY VISITS?
The study doctor or study staff will do the things listed below when you come in for study visits.

• **Personal questions:** At the first visit, you will be asked to give identifying information about yourself, such as name, date of birth and race.

• **Health and medication questions:** You will be asked to answer questions about your health, hair loss and medical history (including HIV status) and medications. At every visit, you will be asked about how you have been feeling.

• **Vital signs:** Your blood pressure, heart rate (pulse), and respiratory rate will be measured at every visit.

• **Height, weight:** You will be measured to see how tall you are (at screening) and how much you weigh (at 6 visits).

• **Physical examination:** The study doctor or study staff will examine you to check your health 3 times during the study.

• **Laboratory tests**:

o **Blood sample** - About 1 teaspoon of your blood will be obtained up to 6 times during the study for routine clinical tests to check your health.

o **Testing for differences in gene (CRTH2) that might be linked to hair loss (AGA) -** An additional 10 mL (2 teaspoons) of your blood will be collected at

screening to test if there are any differences in a gene (called CRTH2) that may help predict how people respond to setipiprant. You can ask the study doctor if you have questions about this testing. The results of this testing will be linked to the overall study results. However, your individual results will not be provided to you or your study doctor, nor will they be placed in your regular medical records. Your samples will be destroyed within 24 months of the end of the study.

• **Urine sample:** Your urine will be collected up to 6 times during the study for routine clinical tests (urinalysis) and a drug screening. At screening, the urine will be tested for the presence of various prescription and illegal drugs, including opiates (narcotic pain killers), cocaine, methadone, barbiturates, benzodiazepines. amphetamines, phencyclidine, cotinine, and ethanol (alcohol). The drug screening is performed for study compliance. If your results are positive, you will not be able to participate in this study.

The positive results will not be reported to any local or federal agencies. You may request a copy of your lab results for yourself or your Primary Care Physician.

Your blood and urine ("Specimens") will be collected for this Study. Specimens collected shall become the property of Allergan. There is a remote possibility that your Specimen(s) may become part of a process or product that ultimately may have commercial value; should this occur, the rights to any profits from this commercial process or product would belong to Allergan. Your samples will be destroyed at the end of the study.

• **Electrocardiograms:** An electrocardiogram (ECG) will be done up to 4 times during the study. An ECG is a recording of the electrical activity of your heart.

• **Photographic Procedures:** Photographs will be taken of the balding area at the back of your head at 6 clinic visits.

o *Micro-dot tattoo:* At the Day 1 (baseline) visit, two tiny ink dots (microdots) will be placed where the balding area starts towards the front of your head. Using these tiny dots will help the study staff to go back to the same site throughout the study to take an image to look for new hair growth. These microdots could fade over time and may need to be refreshed one or more times during the study.

o *Hair clipping:* After global photography at the baseline/randomization, week 8, week 16, week 24, and week 32 visits, the study staff will clip the hair to approximately 1 mm (0.04") in length in the target areas (a circle around the ink dots, approximately 1.8 cm or less than ¾ inch in diameter).

• **Questionnaires/Interviews:** You will be asked to rate your level of satisfaction with your hair, answer questions that describe your hair loss, and answer questions that describe the impact of your hair loss. You will be asked to view photos of the balding

area at the back of your head, and answer questions that describe the hair growth in the photographs.

• **Study treatment:**

o Starting at the Baseline/Randomization visit (Visit 2), you will be given:

 "Weekly Wallets" containing study medication (if you have been assigned to the setipiprant or placebo groups).You will take 2 tablets of study treatment with water by mouth twice a day. The doses should be taken approximately 12 hours apart, at least 1 hour before or 2 hours after eating (for example, 1 hour before breakfast in the morning and at least 2 hours after dinner).

 A bottle containing finasteride 1 mg tablets (if you have been assigned to the finasteride 1 mg group). You will take 1 tablet with water by mouth once a day.

o You will be given written instructions describing how to administer the study treatment. The wallets or bottles and any unused study treatment must be returned at the next study visit.

o Please do not discuss the type of treatment you receive with the doctor who will complete the hair questionnaires during your visits.

As part of this research study, you will be photographed.. If you do not want to have the photographs taken, you cannot participate in the study. This is being done because Allergan may use the photographs to evaluate the results of the study and/or for general research, education, or informational purposes. Allergan, PLC may also use the photographs for marketing and advertising purposes. You understand that you may request the photography be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photograph before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs, videotapes, audiotapes or other media (including articles containing such) before they are used in this study.

Allergan, PLC will own the copyright of the photographs.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

As part of this study, a blood sample will be obtained and DNA from your blood sample will be purified. DNA, or deoxyribonucleic acid, stores and transmits inherited traits, such as eye color or blood type. As part of this research project, the sponsor wants to see if one gene (called CRTH2) affects the way people respond to setipiprant. Because we do not know how the results of this test relate to your individual health, the results of the research will not be given to you or your doctor. These results will also not be placed in your medical records.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 36 weeks and have a total of 7 study visits.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures and study medications we are studying include:

Risks of the Study Drug

Setipiprant has been studied previously in greater than 1000 subjects with treatment durations less than or equal to 12 weeks. If you are in the group which is assigned setipiprant, you may experience the following risks which were identified in 569 subjects who received 1000 mg of setipiprant in previous clinical trials:

- Asthma: 6 (1.1%) of study participants experienced
- Headache: 15 (2.6%) of study participants experienced
- Nasopharyngitis (inflammation of the nose and the part inside your mouth where the passages of the nose connect to your mouth and throat): 3 (0.5%) of study participants experienced
- Shortness of breath: 9 (1.6%) of study participants experienced
- Diarrhea: 7 (1.2%) of study participants experienced
- Upper respiratory tract infection: 4 (0.7) of study participants experienced
- Nausea: 5 (0.9%) of study participants experienced

There may also be other risks to septipiprant that are unknown.

Risks associated with Active Comparator

If you are in the group which is assigned finasteride, you may experience the following risks:

- Sexual dysfunction may continue after discontinuation of treatment, including erectile dysfunction, libido disorders, ejaculation disorders, and orgasm disorder; male infertility and/or poor seminal quality (normalization or improvement of seminal quality has been reported after discontinuation of finasteride).
- Hypersensitivity reactions such as rash, itching and swelling of the lips, tongue,

throat, and face.
- Male breast cancer, breast tenderness and enlargement
- Depression.
- A subsequent potential risk to a male fetus if pregnant or potentially pregnant women handle crushed or broken finasteride tablets.
- Decreased Prostate Specific Antigen (PSA: In clinical studies with finasteride (1 mg), in men 18-41 years of age, the PSA decreased from 0.7 ng/mL at baseline to 0.5 ng/mL at month 12. In clinical studies with finasteride (5 mg), in older men with benign prostatic hyperplasia, PSA levels decreased by approximately 50%. Other studies with finasteride showed it may also cause decreases in serum PSA in the presence of prostate cancer. Any confirmed increase from the lowest PSA value while on finasteride may signal the presence of prostate cancer and should be evaluated. even if PSA levels are still within the normal range for men taking finasteride. Non-compliance to therapy with finasteride may also affect PSA test results.• Increased risk of high-grade prostate cancer: Men aged 55 and over with a normal digital rectal examination and PSA ≤3.0 ng/L at baseline taking finasteride 5 mg/day in the 7-year Prostate Cancer Prevention Trial had an increased risk of high-grade prostate cancer.

Placebo Risks
If you are assigned placebo (the medically inactive substance), your symptoms of AGA may not improve or get worse. This is because you will not be getting any active treatment for your condition.

Other Risks
Blood Sample Risks
You may feel a slight needle prick when blood is drawn. Some patients may have a slight bruise that will go away within a few days. Sometimes, patients feel light headed or feel dizzy. Other rare complications associated with the blood sample collection include: infections, nerve lesions, accidental arterial puncture (when the needle pierces an artery instead of a vein) and bleeding, inflammation of vein, and dizziness.

Electrocardiogram (ECG) Risks
The ECG procedure may cause minimal discomfort and skin irritation during or after the attachment and removal of the leads (and adhesive).

Allergic Reaction Risks for Drug Studies
As with taking any treatment, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:
- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse

• Sweating

Please seek medical treatment immediately and tell the study doctor and study staff if you have any of these symptoms, or any other side effects, during the study. In the case of an emergency, call 911.

Personal Questions Risks

You will be asked questions about personal issues during this study including questions about your AGA. These types of personal questions may make some subjects uncomfortable.

Unknown/Unforeseen Risks

In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this study treatment. Since the study treatment is investigational, when taken alone or in combination with other medications, there may be other risks that are unknown. Tell the study doctor or study staff right away if you have any problems.

You will be informed verbally and in writing of any new information, findings, or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

If you experience any side effects or research-related injury, contact Dr. Amy McMichael immediately at (336) 716-3775 or (336) 716-2011.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Reproductive Risks and other Issues to Participating in Research

Contraceptive Measures for Males

Your participation in this research study may damage your sperm, which could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this. Medically acceptable contraceptives include: (1) surgical sterilization (such as a vasectomy), or (2) a condom used with a spermicide. Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use.

You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should also promptly notify her doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefit of participating in this study may be: possible prevention of further hair loss,.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

Topical solutions/foams
Oral Corticosteroids
Intralesional Corticosteroids

The benefits for using the alternative treatment is improvement in hair count and thickness is possible.

The risks include contact dermatitis and reduction in incidence of pruritus.
You could be treated with Minoxidil (Rogaine®) or Finasteride (Propecia®) even if you do not take part in the study.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and/or effectiveness of (KYTH-105) Setipiprant tablets ; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a research study. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

WILL YOU BE PAID FOR PARTICIPATING?

If you meet all the eligibility criteria for the study, are enrolled, and complete all the scheduled study visits, you will be paid $350.00. If you withdraw for any reason from the study before completion you will be paid $50.00 for each complete study visit.

In order to determine eligibility for the study, a screening visit will be conducted. You will be paid $50.00 for this screening visit, if ALL required eligibility tests/procedures are completed. To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid. You will receive no payment or other compensation for taking part in this study.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Allergan plc. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. Dr. Amy McMichael has a relationship with Allergan and receives compensation, separate from this study, for consulting services.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Sponsor shall be responsible for any reasonable and necessary medical expenses incurred by Study Subjects for medical care, including hospitalization, in the treatment of adverse reactions arising from the Study drugs, devices, interventions or procedures and tests administered in accordance with the Protocol. Notwithstanding the foregoing however, Sponsor will not be responsible for such costs to the extent the injury, illness or condition is attributable to or arises out of the negligence, willful misconduct or nonfeasance of Institution, Principal Investigator or any Study Staff. Sponsor is not responsible for expenses that are due to pre-existing medical conditions or underlying disease.

If you are injured, the insurer may require information such as your name, social security

number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Amy McMichael at (336) 716-3775 and after hours: (336) 716-2011.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you] and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** demographic information (such as address, phone number, E-mail address, gender, date of birth and race), clinical office notes and laboratory results.

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If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or

recorded media which are identifiable.

1) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

2) Representatives from government agencies such as the US Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS)*/*.

3) Representatives from government agencies such as the Office for Human Research Protections and other similar agencies.

4) Sponsor, including its affiliates, agents, and contractors

5) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept until at least two years after the last approval of a marketing application, there are no pending marketing applications, or 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. . You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.
You can tell Dr. Amy McMichael that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Amy McMichael, MD
4618 Country Club Road.
Winston Salem, NC 27104

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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 Web site at any time.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Amy McMichael at (336) 716-3775 or after hours (336) 716-2011.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____ Date:_____ Time:_____ am pm