Participant Name: _____ Date:_____

Title of Study: CSP#594 Comparative Effectiveness in Gout: Allopurinol versus Febuxostat

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: James O'Dell, MD

INTRODUCTION

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely; if you wish, you can discuss it with family and friends. If there is anything that is not clear or if you would like more details please ask one of the study staff to explain them to you. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

What is the purpose of this research study?

The purpose of this research study is to find out whether the two medications Allopurinol and Febuxostat work as well as each other for preventing gout attacks. This is a double blind placebo controlled study meaning you will not know which treatment you are receiving during the duration of the study. Both of these medications have been approved and are currently used to prevent gout attacks, though the FDA recommends that allopurinol be tried first.. They work by lowering the level of uric acid in your body that causes gout attacks. However, we do not know which medication is best, what doses are needed to gain the most benefit, or whether certain patients may do better with one medication or the other.

We will also determine which medication may be more effective in treating patients who have gout and who also have decreased kidney function. Gout is a common disease among Veteran patients and treating it more effectively and efficiently to prevent gout attacks is an important goal for the VA.

Why am I being asked to participate in this research study?

You are being asked to participate in this research study because you have a history of gout and your recent blood uric acid level is at a high level when gout attacks may occur.

What kind of treatment would I receive if I wasn't in this research study?
If you were not in the research study, the treatment you would receive for your gout would be handled by your regular doctor. That treatment may include allopurinol or febuxostat or any other medications used to lower uric acid or prevent gout attacks.

What are the treatments I will receive as part of this research study and are these treatments approved by the Food and Drug Administration (FDA)?
As part of this study, you will be assigned by chance (like a flip of a coin) to receive either allopurinol or febuxostat. You would have a 50:50 chance of receiving either medication. Allopurinol and febuxostat have both been shown to be effective in gout and are approved by the FDA; however, febuxostat is only recommended for patients whose gout is not controlled with or cannot tolerate allopurinol.

Who will be conducting the research study and who is sponsoring this research?
This study is being conducted at < insert VA name > as well as other VA and non-VA hospitals across the United States and is being sponsored by the Department of Veterans Affairs.

How many people are going to participate in this research study?
There will be about 950 participants in the study from about 20 VA Medical Centers located all across the US. Locally at <insert VA name>.

DURATION OF THE RESEARCH

Your individual participation in the project will take 72 weeks (approximately 18 months), during which you will be taking study medications. We will check your medical records 30 days later to see if you report any gout related issues. This research study overall is expected to take approximately 4 years (48 months) for all participants to complete. We will continue to review your medical records for 10 years to track your health (review will be conducted up to10 years after the last participant's final study visit); however, we will not need to contact you during this time. This is a 72 week blinded study, therefore the blind will be broken and care will be returned to your primary care doctor. Information on your gout control will be available to your doctor and the study drug that you were receiving will be known. Treatment decisions after the study will be up to your primary care doctor's discretion. Data will be revealed at the end of the 72 weeks.

STUDY PROCEDURES

Initial/Screening Visit

After you sign this consent form, we need some additional information to see if you can continue in the full study. We will ask you questions about your gout condition to determine your eligibility. You will be asked about any prescribed and over-the-counter medications you are taking. We will draw a sample of blood (about 2 tablespoons) to check your uric acid level, liver and kidney function. Drawing blood involves venipuncture (a small needle is inserted into a vein in your forearm). This visit will take approximately 1 hour of your time.

Initial/Screening Visit (cont'd)

If any information from the initial screening visit indicates that you are not eligible for the study, you will be referred to your doctor to continue your regular care based on his or her advice. If after the screening tests you are considered eligible to continue in the study, you will be scheduled for a study entry visit. This visit can be done either at the same time as your screening visit if your eligibility is confirmed then, or you will be asked to return within 2 weeks of your screening visit.

Study entry visit

You will be randomized to receive either allopurinol or febuxostat, having a 50:50 chance to receive either medication. You will receive two sets of study pills to take at the same time. One set will be the actual medication; the other set will look like the other medication, but it will in fact be a placebo (an inactive sugar pill). Neither you, the research team nor your regular doctors will know which active medication and which placebo you are receiving. This visit will take up to 2 hours.

While in the research study, you will be asked to take the study medications for 72 weeks. Both sets of pills (active and placebo) can be taken at the same time, morning or evening, with or without food. While in this study you will be asked not to make any changes in any of your other medications unless absolutely necessary, and only with permission of your doctor. The research team will be available to you for any questions regarding the study medications and how you should take them.

At the study entry visit, you will be asked to complete several questionnaires about your health-related quality of life and alcohol use, have blood pressure and weight measured, and have a blood test (about two tablespoons) to measure blood counts and inflammation in your body. These blood tests will include:

- Complete blood count (CBC)
- Tests to measure the level of uric acid in your blood
- Tests to measure the function of your liver and kidneys (standard blood tests your doctor would order to monitor the effect of the medications on your body).
- Tests to measure inflammation in the body

In-person study visits (until week 48)

You will come to the Study Center every six (6) weeks for blood tests and evaluation by the study doctor and/or study coordinator. At each visit you will have your blood pressure taken, and you will talk with the physician and discuss any side effects you may be having and any changes in your medications, your gout and your general health. You will also be asked about taking your study medication, and may have your dose increased based on the results of your blood tests. At the week 24 visit, you will be asked to complete questionnaires about your health (the same as at the beginning of the study). These visits will take approximately 30 minutes of your time and are very important to make sure you are receiving the correct dose of study medication to treat your symptoms.

Blood tests: To monitor for side effects and how well the medication is working, the same amount of blood (approximately 2 tablespoons) will be drawn again every 6 weeks for 48 weeks. You may also need to have blood tests for uric acid level done at weeks 9, 15 and 21 if your uric acid level remains too high. These blood tests will include those you will receive during your study entry visit.

Phone visits

Starting at week 3, the study coordinator will call you every six weeks until week 21 (weeks 3, 6, 9, 15, 21), then again at weeks 30 and 42 to discuss medication side effects, any changes in your gout, and whether you have been taking the study medication as prescribed. These phone calls will occur on the weeks between your in-person visits to the Study Center (for example, phone call at week 3 and in-person study visit at week 6). These phone calls will take approximately 5-10 minutes of your time.

In-person 48-week visit

At the 48 week visit, or if you leave the study early, you will have blood pressure and weight measurements, blood tests done, and you will complete the same questionnaires about your health and alcohol use as at the beginning of the study. You will also be asked about any side effects, medication changes, taking your study medications, and will be asked to return your unused study medications. This visit will take up to 2 hours.

Study visits (phone and in-person) after 48 weeks

Active treatment with the study medications ends at 72 weeks. After you have had your 48 week visit, we will be calling you every 4 weeks to ask about any gout attacks that you may have had and whether you have been taking the study medication as prescribed. These phone calls will take approximately 5-10 minutes of your time at weeks 52, 56, -, 64, and 68. At week 60 and 72, or if you leave the study early we will ask you to come for an in-person study visit. You will have blood pressure and weight measurements taken, blood tests done, you will also be asked about any side effects, medication changes, taking your study medication,and any gout attacks. You will also be asked to return your unused study medications. This visit will take up to 2 hours. In addition, at week 72 you will complete the same questionnaires about your health and alcohol use as at the beginning of the study..

Gout Attack Diary

We will ask you to keep a diary of gout attacks that occur in between study visits and phone calls so that it's easier for you to remember information about the gout attack when they are discussed during your study visits. These diaries will ask you a few specific questions about your gout attacks that occur in between study visits.

After study participation has ended

After you complete study participation, during which you will be taking study medications, you and your doctor will be told which drug you were taking (allopurinol or febuxostat). This is so that after the study your provider has the information to treat your gout appropriately. We will check your medical record 30 days later to see how you are doing and whether you reported any gout-related complaints to your doctor.

POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unexpected) risks also may occur. The following is not an all-inclusive list, but includes conditions that are more likely to occur than others. Rare, unknown, or unforeseeable (unexpected) risks also may occur. For more information about allopurinol or febuxostat you may consult further with the study doctor or refer to a standard text such as the Physicians' Desk Reference (PDR) or the United States Pharmacopoeia Dispensing Information (USPDI).

Risks and side effects related to allopurinol are listed below:

- The most common side effects reported by patients or detected by doctors include: mild skin rash, gout attack, loose stools (diarrhea), upset stomach, nausea, and increased liver proteins.
    - As we adjust the dose to lower your uric acid levels, allopurinol may cause you to experience an increase in gout attacks, but this should go away after the first few weeks. You will be given medications to minimize this temporary risk of gout attacks.
- Less frequent side effects, reported by patients or detected by doctors less than 1% of the time, include moderate to severe skin reactions, decreased blood cell or platelet count, liver damage, kidney problems, and general allergic reaction. Although these side effects are very rare, some may be more serious than the more common side effects.
    - Skin reactions can range from a mild rash to a severe skin reaction. Symptoms of this allergic reaction may include bumps, spots or blisters on the skin, large areas of peeling skin, and sores in and around the eyes and mouth. The skin and eye reactions may also be accompanied by other whole-body symptoms such as itching, body aches, and fever, and can damage your liver and kidneys. You will be monitored closely for skin reactions.
    - Symptoms of general allergic reaction can include similar symptoms to skin reaction but also swelling and/or tightening of the chest, face and/or throat. Very rarely, these reactions can be life threatening. Please notify your study doctor immediately if you are having an allergic reaction. Promptly stopping the medications reduces the risk of life threatening complications.
    - Liver problems can range from mildly increased liver proteins to severe liver damage. Signs of liver problems include dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes. Please notify your study doctor immediately if you are having any of these symptoms.

Risks and side effects related to febuxostat are listed below:

- The most common side effects reported by patients or detected by doctors between 1 to 10% of the time include: mild skin rash, joint pain, gout attack, upset stomach, nausea, dizziness, and increased liver proteins.
    - As we adjust the dose to lower your uric acid levels, febuxostat may cause you to experience an increase in gout attacks, but this should go away after the first few weeks. You will be given medications to minimize this temporary risk of gout attacks.

- Less frequent side effects, reported by patients or detected by doctors less than 1% of the time, include moderate to severe skin reactions, decreased blood cell or platelet count, liver damage, mood changes, heart and blood vessel problems including a heart attack or stroke, and general allergic reaction. Although these side effects are very rare, some may be more serious than the more common side effects.
    - Skin reactions can range from a mild rash to a severe skin reaction. Symptoms of this allergic reaction may include bumps, spots or blisters on the skin, large areas of peeling skin, and sores in and around the eyes and mouth. The skin and eye reactions may also be accompanied by other whole-body symptoms such as itching, body aches, and fever, and can damage your liver and kidneys. You will be monitored closely for skin reactions.
    - Symptoms of general allergic reaction can include similar symptoms to skin reaction but also swelling and/or tightening of the chest, face and/or throat. Very rarely, these reactions can be life threatening. Please notify your study doctor immediately if you are having an allergic reaction. Promptly stopping the medications reduces the risk of life threatening complications.
    - Liver problems can range from mildly increased liver proteins to moderate liver damage. Signs of liver problems include dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes. Please notify your study doctor immediately if you are having any of these symptoms.
    - May increase the risk of heart-related death and death from all causes compared to allopurinol, in people who already have heart disease. This study will help us understand any difference in heart and blood vessel problems between these two approaches to treating your gout.You should call your doctor or get emergency help right away if you have any of the following symptoms:
        - Chest pain
        - Numbness or weakness in one side of your body
        - Shortness of breath or trouble breathing
        - Slurring of speech
        - Dizziness, fainting or feeling lightheaded
        - Rapid or irregular heartbeat

Contact your study doctor right away if you experience any of these side effects or any other unusual symptoms. Your study doctor will be following you to see if any side effects from any of these medications occur, and will manage these symptoms with treatments that are appropriate for you. We will also follow your blood counts, kidney and liver function test closely during the study. It is important that you report promptly any side effect experienced to your study doctor. If you or your study doctors feel that the side effects are not acceptable, study medications may

be stopped altogether. There may be some risk for those patients taking higher doses of febuxostat that have not yet been approved by the FDA, but it is approved and widely used outside the U.S. The study team will continue to monitor your health throughout the study in order to minimize this risk. If toxicity develops and the toxicity is severe enough to require your removal from the protocol then the blind will be broken meaning you and your physician will be informed of the drug you were receiving during your participation in this study.

Prophylatic medications such as colchicine, naproxen or prednisone will be given to you to help prevent flares. These medications are given to you while you are at an increased risk of flares, including while your uric acid levels are going down. For this study these medications will be stopped at week 48. Stopping these prophylactic medications, for some subjects, may slightly increase the chance of experiencing the symptoms of a gout flare. Importantly, the urate lowering medications, Allopurinol or Febuxostat will of course be continued. If flare symptoms occur, contact the appropriate study staff personnel for further guidance.

We will make every effort to make study visits and phone calls as convenient for you as possible by scheduling your research visits during your regular clinic visits. You will have blood drawn up to 14 times over the course of the study to review and adjust your medications. The needle sticks from having blood drawn may cause pain (like a pinch), or bruising, and, rarely, infections. Very rarely, patients become lightheaded or faint from having blood drawn.

We do not anticipate side effects from the placebo for Allopurinol or for Febuxostat. It has been shown in some studies that the psychological impact of a placebo may cause side effects similar to those described for a study treatment in some participants.

Blood draw may cause pain and a bruise. Some people may become light-headed (dizzy) or faint after blood drawing. There is also a rare risk of infection at the site of the blood draw.

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening (see "Confidentiality" section below)

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

POTENTIAL BENEFITS

- *Advancement in knowledge regarding treatment practices in gout will be of scientific and public health value*
- *Participating subjects may benefit from increased monitoring that is related to study participation*
- *Participating subjects may also benefit from better control of uric acid and therefore fewer gout attacks.*

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

If you chose not to participate your doctor will continue to treat you just as they did before. Both of the medications studied in this trial are available to be used. In some cases at the VA, physicians are required to use allopurinol before febuxostat is tried.

You may discuss these options with your doctor.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. Confidentiality cannot be guaranteed, but your private information will be protected in a number of ways. The study team will keep all research records that contain your identifiable health information confidential to the extent allowed by law. All hard-copy study forms with the information we collect from you as part of this study will be stored in locked cabinets to which only approved study staff will have access. Data will be entered on computers that are protected with passwords to which only approved study personnel will have access. Only approved study staff at the study's Coordinating Center will have access to participant identifying information. This study is being conducted in multiple VA Medical Centers nationwide. Information shared among researchers will not be able to identify you individually. This study is also being conducted in multiple sites in the Rheumatology and Arthritis Investigational Network (RAIN) across the US.

The study team will collect your Social Security number for this research study. The study team will use your Social Security number only as necessary within the VA to search your medical records or when there is a need to check your non-VA hospitalizations during the study or to check your status with other healthcare and vital status databases. We use a unique code instead of your name or Social Security number to identify you in our study database. If you choose to withhold your Social Security number, you will not be able to participate in the study.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you individually.

Research records, just like hospital medical records, may be released or disclosed according to applicable federal and state law as well as to federal and state agencies that are responsible for oversight of medical research. We will not share your records or identify you unless we have to by law. A researcher with IRB approval may gain access to a dataset that includes your information but does not identify you. There are times when we may have to show your records to other people including representatives of the sponsors of this study or the Food and Drug Administration (FDA). In addition someone from the Department of Health and Human Services, Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

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.

We will put information about you from this study into your medical record. This includes putting a progress note in your computerized VA medical record that states you are participating in a research study.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants: You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

Payment Offered for Participation: You will not be paid for participation in this study, but we will pay for transportation, parking, or other expenses related to participation, up to $40 per visit. The amount that you are reimbursed will be based on the number of miles that you travel for your visits. Specifically, participants who travel less than 50 miles will receive $20 and participants who travel 50 miles or more will receive $40. Reimbursement will be made available by <insert site specific info>. Due to limitations in the Financial Management System, payments made to participants through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. Your SSN will be used for this purpose in reimbursement.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Dr./Mr./Ms. _____ at _____ and

AFTER HOURS:

Dr. /Mr./Ms._____ at _____.

Emergency and ongoing medical treatment will be provided as needed.

The major complications of uric acid lowering therapy, either allopurinol or febuxostat, are gout attacks and rashes. Medications to treat any gout attacks will be provided as part of the study and all participants will be monitored closely for rashes. Study medications may be stopped or doses decreased if any rashes occur.
You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you decide to not take your medications your blood uric acid level will increase and you will again be likely to experience attacks of your gout which could include painful and swollen joints.

If it is necessary to withdraw from the study your rheumatologist or primary care doctor will treat your gout.

You may contact study personnel at any time if you would like to withdraw from the study. Contact information can be found in the section below titled, "Persons to Contact About This Study" If you withdraw, study personnel may continue to review the study data already collected prior to your withdrawal, but they cannot collect further information about you, except from public records, such as survival data. Specimens that have already been used cannot be withdrawn.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The investigator(s) may stop your participation in this study, without your consent, for reasons such as: it will be in your best interest; you do not follow study procedures; or you experience a study-related injury.

PERSONS TO CONTACT ABOUT THIS STUDY

If you have any questions, complaints, or concerns about this study, you may contact the study investigator at your VA Medical Center or the <insert info> during regular business hours.

The investigator is Dr./Mr./Ms. _____at_____

The <insert info> is Dr. /Mr./Ms._____at _____.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

After this study ends, your study data will be stored indefinitely at the Cooperative Study Program, Massachusetts Veterans Epidemiology Research and Information Center (The future use and re-contact for this data will be different than the data storage of the biobanking of specimens described below).

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: **04/05/2019**

LSI Approval Date: **N/A**

LSI Verification Date: **N/A**

Study data will be available for use for approved research protocols by investigators who may or may not be associated with this study. Researchers may link your study data with existing data sets, including but not limited to those maintained by the Social Security Administration, Department of Veterans Affairs or other organizations. Any use of your data will comply with existing regulations and be approved by appropriate oversight bodies including an Institutional Review Board (IRB). The IRB is a group of people, unrelated to the study, who review research studies to make sure your rights are protected. The IRB may require that you be contacted for your consent prior to the use of your data in a new study if it decides such consent is required for your protection. By signing this consent form you are agreeing to be re-contacted in the future to request your permission for the use of your data in a new study, you may deny this permission for future use and still be eligible to participate in this study.

BIO-BANKING OF SPECIMENS FOR AN OPTIONAL PART OF THE STUDY

You are being invited to participate in an optional part of the study that will collect blood for future research on how your genes and markers of inflammation in the blood influence gout attacks, your response to gout therapies and the overall health of patients with gout.
Please read each sentence below, think about your choice, and mark "**YES**" or "**NO**". **No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.**

If you agree to participate, we will collect 2 tablespoons of blood at your screening and/or baseline, 24 week and 48 week visits.. If you are eligible to participate in this study this extra blood will be banked at the Experimental Immunology Laboratory (EIL) centered at the VA Nebraska-Western Iowa Health Care System indefinitely. This is VA a approved biobank. The long-term storage of your samples will be overseen by the Omaha VAMC Institutional Review Board, which is a group of people, unrelated to the study, who review research studies to make sure your rights are protected. Only approved study personnel will have access to your specimens for this study. No samples will be removed or used from the bank until completion of the research study. Any future proposal to test your blood and/or DNA samples will need to be approved by the appropriate oversight bodies. If any information from the initial screening visit indicates that you are not eligible for the study, the extra blood will not be stored and will be destroyed following local policies and procedures.

You will not be re-contacted about any future use of your samples. All samples sent for biobanking will be marked only with a unique study ID but will not include any Protected Health Information. These samples, however, can be linked with data collected as part of this research study. The research results from future use of these samples will not be conveyed to you, your family, or physician. If you agree to have your sample(s) stored in the Repository, you

can change your mind up until the end of the research study. If you change your mind before the research ends you can send a letter to:

Dr. Ted Mikuls MD
983025 Nebraska Medical Center
Emile at 45th Street
Omaha NE 68198-3025

requesting withdrawl from the biobank study. When study researchers receive written instructions from you, they will destroy your samples and all information in the repository that identifies you. After the research study ends, you will not be able to withdraw your samples because the Repository will not know which one is yours. The samples will stay in the Respository indefinitely.

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening.
Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A new federal law, the Genetic Information Nondiscrimination Act (GINA) generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information obtained from this research.
- Health insurance companies and group health plans may not use your genetic information obtained from this research when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained 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.

If you have any questions or concerns about biobanking of your samples you may contact Dr. Ted Mikuls M.D. during during regular business hours at 402-888-0515

☐ **YES** **My specimen(s) may be saved for future research without any restrictions.**

OR

☐ **YES** **My specimen(s) may be saved for future research with the following restrictions.**

Check ALL the restrictions that apply:

☐ **My specimens can only be used for research by the current principal investigator**

☐ **My specimens can only be used for research that does not involve genetic testing**

☐ **My specimens can only be used for research that involves the disease or condition to which this study pertains**
OR

☐ **NO** **I do not wish to participate.**

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the study staff has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: **04/05/2019**

LSI Approval Date: **N/A**

LSI Verification Date: **N/A**

Participant Name: _____ Date:_____

Title of Study: CSP#594 Comparative Effectiveness in Gout: Allopurinol versus Febuxostat

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: James O'Dell, MD

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date

SUBJECT'S IDENTIFICATION

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 04/05/2019

LSI Approval Date: N/A

LSI Verification Date: N/A