Department of Veterans Affairs

RESEARCH CONSENT FORM

Version Date: 02/12/2020 [redacted]

Participant Name: _____ Date: _____
Last, First, MI Suffix

Title of Study: M16-011: A Phase 3, Randomized, Double-Blind, Study Comparing Risankizumab to Placebo in Subjects with Active Psoriatic Arthritis (PsA) Who Have a History of Inadequate Response to or Intolerance to at Least One Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy

Principal Investigator: [redacted] MD VA Facility: [redacted]

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is about a drug called risankizumab (ABBV-066). It is being funded by AbbVie, Inc. [redacted] By doing this study we hope to learn about the safety and effectiveness of the drug in the treatment of psoriatic arthritis (PsA).

Risankizumab is an investigational drug. An investigational drug is one that has not been approved by the Food and Drug Administration (FDA). Risankizumab is made in the laboratory and is a monoclonal antibody which means it is the same as a protein in your body, called an antibody. It works by blocking the actions of a protein known as Interleukin 23. Interleukin 23 is involved in the immune response and plays an important role in the development of chronic inflammation. Risankizumab is being studied in patients with PsA and other inflammatory disease.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

Your participation in the study could last up to approximately 233 weeks (4.5 years).

- Screening Period – about 35 days (5 weeks)
- Period 1 – Treatment period from Baseline/Day 1 to Week 24 (about 6 months)
- Period 2 – Treatment period from Week 24 through Week 208 (about 3½ years)
- Follow-up Period – 20 Weeks (5 months)

The purpose of this research is to gather information on the safety and effectiveness of risankizumab. To do this will require regular visits to the [redacted] Research Clinic to assess your eligibility for the study and then, if you are eligible to participate, to assess how well you are tolerating the medication and how well it is working to alleviate your signs and symptoms of PsA. The medication is given by subcutaneous injection (just under the skin).

The Clinic visits will last from 1½ to 3 hours and will always involve a blood draw of about 1½ teaspoons. A urine sample may also be collected if you are a female of childbearing potential.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may consider volunteering for this study because you have moderately to severely active PsA and have not responded well to treatment with 1 or more conventional synthetic Disease Modifying Anti-Rheumatic Drugs (csDMARD) like sulfasalazine, methotrexate, ciclosporin A, Etc. or you are intolerant to DMARDs. For a complete description of benefits, refer to the Research Details.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might not choose to volunteer for this study because of the time commitment, the distance to travel, or the risks of the study drug or procedures involved as outlined in the Research Details.

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Principal Investigator: [redacted] MD VA Facility: [redacted]

As noted above, you are being invited to participate in this study because alternative treatment has not worked well for you. These treatments include other biologic medicines and/or csDMARD therapy. Some other-the-counter nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen have been known to help reduce inflammation, pain and swelling. You should contact your personal physician for more information on options that would be appropriate for you.

For a complete description of risks, refer to the Research Details below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [redacted] MD, Principal Investigator, PI of the [redacted] VA Health Care System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study [redacted] contact information is: [redacted]

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn how well 150mg of risankizumab works (efficacy) and how safe it is for the treatment of signs and symptoms of psoriatic arthritis (PsA). Subjects who have moderately to severely active PsA and who do not respond to treatment after at least 12 weeks of therapy or subjects who cannot take 1 or more conventional synthetic Disease Modifying Anti-Rheumatic Drugs (csDMARD) are being asked to participate.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 5 years. Your individual participation in this study could last up to approximately 233 weeks (4.5 years). A total of 25 individuals will be asked to participate in this study at the [redacted] VA Health Care System [redacted] Overall, a total of approximately 880 individuals will be enrolled at approximately 270 research study centers in about 40 countries

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

The Principal Investigator or a member of her study staff will discuss the requirements for participation in this study with you. To participate in this study, you must meet eligibility criteria. You must be at least 18 years of age and have been diagnosed as having PsA at least 6 months prior to signing this form. You must also have signs and symptoms of the disease (swollen tender joints; evidence of plaques, Etc.) documented at both the Screening Visit and Baseline (Day 1 of study drug treatment). There must also be documentation that prior

treatment for your PsA has failed. These treatments include DMARDs (sulfasalazine, methotrexate, ciclosporin A, Etc.). Intolerance to DMARDs may also be considered by the study doctor.

The following information describes your participation in this study which could last up to approximately 233 weeks (4.5 years).

- Screening Period – about 35 days (5 weeks)
- Period 1 – Treatment period from Baseline/Day 1 to Week 24 (about 6 months)
- Period 2 – Treatment period from Week 24 through Week 208 (about 3½ years)
- Follow-up Period – 20 weeks (5 months)

Screening Period:
During the Screening Period the study will be explained to you and all your questions will be answered. If you agree to be in this study, you will sign this Consent Form and then undergo some activities, tests and evaluations to determine if you are eligible for participation. Each visit could take from 1 to 3 hours of your time. Such tests and evaluations are completed in the 35 days that take place before you receive study drug and include the following:

- Subject information and informed consent signed after reading and all questions have been asked and answered.
- Demographics (age, race, gender) will be recorded.
- Classification Criteria for Psoriatic Arthritis (CASPAR) based on the presence of inflammatory arthritis (joints, spine or connective tissue).
- Medical and surgical history reviewed – questions about your past and present medical condition(s) including asthma symptoms, surgeries, previous vaccinations, tobacco and other nicotine use, and alcohol use.
- Review all medications, skin creams, or any other therapy you are using now or have used in the past.
- Review prior PsA drug(s) and reasons for discontinuing use.
- Your vital signs (height, weight, blood pressure and pulse) will be measured.
- A physical exam will be performed by an investigator who will also evaluate your psoriatic arthritis.
- You may be asked to have x-rays of both hands and both feet if necessary, to confirm you meet certain requirements to participate in the study. The study doctor or site staff member will tell you if x-rays are needed.
- A 12-lead electrocardiogram (ECG) will be performed to test the electrical activity of your heart.
- You will be asked for a urine sample and about 1-1½ tablespoons of blood will be drawn, which may include pregnancy testing if you are a female of childbearing potential. Your blood test at this first visit will also include testing for tuberculosis (TB) and HIV (AIDS), hepatitis B and

hepatitis C.

- The study doctor will oversee your care for any new conditions or abnormalities noted during the screening and may refer you to your primary care physician or other specialist, as appropriate for further treatment.
- An adverse event assessment will be performed to see if you are having any side effects from any of the study testing thus far.
- You will be given a Subject ID card and asked to carry it at all times and to present it to the healthcare provider whenever seeking care outside of scheduled study visits.
- Eligibility criteria will be reviewed after all testing is completed – if you test positive for TB, HIV, hepatitis B or C you will not qualify to participate in this research trial. The study doctor or study staff will tell you if the results are positive. Depending on the local laws, you may have to sign a separate consent form before HIV testing can start. The study doctor or study staff will tell you if the results are positive. If required, the study doctor or study staff may report a positive test result to the local health department. The tests are confidential, and the study doctor or study staff will not share your results outside this study unless local law requires it. A positive result will be documented in your [redacted] patient file.

Period 1:
You will need to fast (nothing to eat or drink except water) for at least 8 hours before the Baseline/Day 1 visit. During Period 1, you will visit the research clinic on Day 1 (Baseline) and also at Week 4, Week 8, Week 12, and Week 16.

If you decide to participate in this study and qualify, at the Baseline/Day 1 visit you will be selected by chance (like the flip of a coin) to receive either risankizumab or placebo (a substance that looks like risankizumab but contains no active medicine) during Period 1. Day 1 will require approximately 3 hours of your time due to the fact that you will be observed for any adverse reaction for 2 hours after your injections. The other visits in Period 1 will require a minimum of 1½ to 2 hours in order to complete a 1-hour post-injection observation time.

The placebo is not a drug, is not expected to have any effects on your body and is not designed to treat any disease or illness. The placebo looks like the study drug to make sure you and the study staff cannot guess what is actually being given to you. This allows the study scientists to make the best judgment on whether the study drug is having effects that are greater than are expected by chance alone. You will have a 50% chance of receiving risankizumab 150mg and a 50% chance of receiving placebo. Neither you nor your study doctor will know which treatment you are assigned to receive. In case of an emergency, your study doctor can find out this information.

Each dose of study drug (risankizumab) or placebo will be given as two subcutaneous injections. A subcutaneous injection (SC) is a shot given into the fat layer just under the skin. In ~~Period 1, SC~~

injections are given at Baseline/Day 1, Week 4, and Week 16. At Week 16, if your condition does not improve enough or becomes worse, your study doctor may add or change the doses of your other PsA medications (rescue medication).

You will be asked to complete electronic questionnaires (instead of paper and pencil) about your psoriatic arthritis and your quality of life, to understand your disease, and your response to study drug. An electronic device (like an iPad notebook) will be used to collect your answers to questions regarding your health. This device meets all regulations for use in clinical studies, including those related to your privacy. Your answers to these questions will be transferred to a storage facility via a secure internet connection and will be viewed by your study site and AbbVie.

You may need to come in for additional (unscheduled) visits in any study period, if necessary, as determined by your study doctor.

Period 2:
Period 2 begins at Week 24 and lasts through Week 208. You will visit the Research Clinic at study Week 24, Week 28, Week 32, Week 36, Week 40, and every 12 weeks after that until Week 208.

During Period 2, all subjects will receive open label risankizumab. To make sure the study doctor does not figure out which study drug subjects were given in Period 1, the subjects who were selected to receive risankizumab in Period 1 will receive placebo injections at the Week 24 visit. This is the only placebo injection that will be received by subjects who are selected to receive risankizumab in Period 1. Subjects who were selected to receive placebo in Period 1 will receive their first subcutaneous injections of risankizumab at Week 24. The Week 24 visit will require approximately 3 hours of your time in order to complete a 2-hour observation period after the injections. At Week 28 and every 12 weeks after that for the rest of Period 2, all subjects will receive risankizumab 150mg injections under the skin and the visits will last a minimum of 1½ to 2 hours due to the 1-hour post-injection observation time.

Starting at Week 36, if your PsA does not improve enough compared to when you started in the study, you will be discontinued from study drug and will be followed up through the end of the study.

Approximately 1½ teaspoons of blood will be drawn at each visit. A urine sample may also be collected if you are a female of childbearing potential.

A premature discontinuation (PD) visit will be completed if you leave the study before the Week 220 visit.

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Principal Investigator: [redacted] MD VA Facility: [redacted]

Follow- Up Period:
During the Follow-up (F/U) Period, you will visit the Research Center for a Completion Visit 12 weeks after the last study drug dose. Approximately 1½ teaspoons of blood will be drawn at each visit. A urine sample may also be collected if you are a female of childbearing potential.

The study doctor or someone from the research site will call you to follow-up by phone 8 weeks later, about 20 weeks after your last study drug dose to talk about any new or ongoing medical conditions.

If you are eligible and agree to participate in this study, you will undergo the study procedures described in the Study Activities Table which can be found at the end of this document.

Subject Responsibilities:
For this study to provide good information about how the study drug works in subjects with your condition, you will be expected to do the following:

- attend all study visits and complete the procedures
- tell the study doctor if you are feeling bad or worse than before
- review all your medications with your study doctor and her research team
- tell your study doctor if you have any changes in medications during the study
- follow the directions of the study doctor and research team
- while participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra x-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.
- fill out questionnaires completely and honestly
- ask questions as you think of them
- fast (nothing to eat or drink except water) for at least 8 hours before the Baseline/Day 1 visit
- carry your subject card with you as long as you are in the study and show it to any medical staff that may be involved in your healthcare
- tell the study doctor or study team member if you wish to stop being in the study

Certain medications you are taking or have taken in the past may keep you from being in this study. Do not change any of your PsA or psoriasis medications or start any new medications without checking with your study doctor.

Pregnancy in Female Participants:
If you become pregnant during this study, you must immediately stop taking study medication and inform your study doctor. The pregnancy will be followed up to determine the outcome. Your permission to follow your pregnancy will be requested. You have the right to refuse to provide this ~~information.~~

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Research Results:
It typically takes 1-2 years after the completion of the trial before the findings are made public and published. You will have the right to contact the study doctor or a member of her team to inquire about any results after you have completed your study participation. Although the study doctor may not be given specific details by the Sponsor, any and all information that is made publicly available about the study at that time will be given to you.

Any general information available during your study participation (e.g., results of blood draws) will be added to your medical chart for access by your primary care provider. Any abnormal results requiring follow-up care will be discussed with you by the study doctor and/or your primary care provider.

At the end of the study, we can inform you as to whether your received Risankizumab or placebo and review with you your individual effectiveness and tolerability results. You will need to give the study team contact information for either yourself or another individual to receive this information.

Clinically Relevant Results
You will receive information on clinically significant test results which may involve follow-up. Results of routine blood tests to monitor your safety will be made available to your primary care provider over the course of the study.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?
You may have side effects while on this study. Taking any medication has potential risks. A specific risk is that the treatment may be less effective than other treatments available. Ask the study investigator if you have any questions about the side effects described here. We will watch everyone in the study for any side effects.

Side effects/adverse reactions may be mild or severe. The study doctor may give you medicine(s) to help lessen any side effects. Some side effects may go away as soon as you stop taking the study drug. In some cases, side effects can be serious, lasting, or may never go away.

Study Drug Risks:
Risankizumab has been given to healthy volunteers and patients with psoriasis, erythrodermic psoriasis (EP), generalized pustular psoriasis (GPP), psoriatic arthritis, Crohn's disease, ankylosing spondylitis, and asthma. Risankizumab has been given either by intravenous infusion (IV, slowly injected into a vein in the arm) or by subcutaneous injection (SC). It has been tested in single doses as high as 1800mg IV and 300mg SC and in repeated doses as high as 1200mg IV and 180mg SC. No new or different side effects were seen with higher doses of risankizumab.

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Principal Investigator: [redacted] MD VA Facility: [redacted]

Taking the study drug in this study may cause you to have one or more of the side effects as listed below.

Over 3000 patients with psoriasis have been treated with risankizumab SC, predominantly with 150mg dose. The rates of overall side effects and serious side effects were similar between risankizumab treatment and placebo treatment (an inactive substance). No new safety risks have been observed with risankizumab compared to the other antibody treatments that affect the immune system and were investigated in the risankizumab clinical development. In clinical trials that compared risankizumab to placebo and either ustekinumab (Stelara®) or adalimumab (Humira®), serious side effects occurred in 2.4% for risankizumab group compared to 4.0% for the placebo group, and 5.0% for the ustekinumab group and 3.0% for the adalimumab group.

In a Phase 2 completed psoriatic arthritis study, 185 patients received either 75mg or 150mg of risankizumab SC or placebo. The most frequent side effects reported in patients who received risankizumab were viral upper respiratory tract infection (common cold caused by a virus) (17.5%), upper respiratory tract infection (common cold) (5.6%), and headache (5.6%).

In a Phase 2 completed Crohn's disease study, 121 patients received 200mg or 600mg risankizumab or placebo by IV. Overall, the number of patients who reported side effects was similar between patients treated with risankizumab and patients treated with placebo. The most frequently reported side effects (≥ 5% of patients) in the risankizumab treatment group were joint pain (17.1%), nausea (15.9%), headache (13.4%), abdominal pain (12.2%), lack of energy (7.3%), fever (7.3%), vomiting (7.3%), and diarrhea (6.1%).

Based on review of all the safety information to date, the following are known risks with risankizumab use:

A. **Common risks** (≥ 10%): may affect more than 1 in 10 people
   - Upper respiratory infections with symptoms such as sore throat and stuffy nose (13%)
B. **Occasional** (≥1% and <10%): may affect up to 1 in 10 people
   - Feeling tired (2.5%)
   - Fungal skin infection (1.1%)
   - Injection site reactions (1.5%)
   - Headache (3.5%)
C. **Rare** (≥0.1%) and <1%
   - Infection of hair follicles (seen as small red bumps on the skin)

Areas of Safety Interest

Infections: Drugs that affect the body's immune system may increase the risk of infections, including tuberculosis (TB). No cases of active TB have been reported in patients treated with risankizumab. You will be screened for signs of active infection before you start on risankizumab. Talk to your doctor before and during use of risankizumab if you:

- currently have an infection or if you have an infection that keeps coming back
- have TB
- have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines while using risankizumab

Injection Site Reactions: Injection of study drug under the skin could result in skin irritation and/or itching, redness, pain, swelling, or hardness at the site of the injection. Also bleeding or bruising at the injection site may occur. Most injection site reactions are not severe and resolve without any treatment but can be uncomfortable for a few hours to a few days.

Other Possible Risks:
Some drugs that affect the immune response have been associated with side effects such as serious allergic reactions, and possible increased risk of malignancy (cancer). These events have not been found associated with risankizumab.

Allergic Reactions: All drugs have a potential risk of an allergic reaction. Allergic reactions may vary from mild (rash, hives, itching) to severe reactions such as anaphylaxis (which may include difficulty breathing, swelling of the face or throat, low blood pressure, or loss of consciousness). A severe allergic reaction requires immediate medical treatment and could result in permanent disability or death. It is important to tell your study doctor about any past allergic reactions that you may have had to other drugs including antibody drugs (which are usually given by IV or injection under the skin). If you seek medical care for a possible allergic reaction, please request the treating health care provider to contact your study physician.

Malignancy (cancer): When an immune system pathway is blocked, there is a possibility of a decreased immune defense against malignancies. In the completed studies to date, risankizumab has not been associated with an increased risk of malignancies but the risk with long term therapy is not known.

Cardiovascular Events: Patients with inflammatory diseases such as psoriasis, psoriatic arthritis, and inflammatory bowel disease have an increased risk of major cardiovascular events (such as heart attacks, strokes or cardiovascular death). In the completed psoriasis studies to date, risankizumab has not shown an increased risk of these events. However, any new or worsening signs or symptoms such as chest, neck or arm pain, shortness of breath, sensation of rapid heart rate, new visual symptoms, or muscle weakness should be immediately reported to your study site and/or primary health care provider.

There is no antidote to risankizumab. Any side effects occurring as a result of risankizumab will be treated symptomatically.

Pregnancy risks, risk to nursing infant and contraceptive precautions:
Risankizumab has not been evaluated in pregnant or nursing women. It is not known if risankizumab is safe for pregnant women, unborn babies and infants or children who are nursing. You may not take part in this study if you are breastfeeding, are pregnant, think that you may be pregnant, or are trying to get pregnant.

If you are a female who can have children, the study doctor or study staff will talk to you about birth control you must use during study participation and 20 weeks after your last dose of study drug. If you are able to become pregnant, you must agree to use at least one of the effective methods of contraception during the study including up to 20 weeks after your last dose of study drug.

Effective methods of contraception acceptable to use during this study are:

- combined (estrogen and progestogen containing) hormonal birth control (oral, intravaginal, transdermal, injectable) associated with inhibition of ovulation (must start at least 1 month prior to Baseline (Day 1)
- progestogen-only hormonal birth control (oral, injectable, implantable) associated with inhibition of ovulation (must start at least 1 month prior to Baseline (Day 1)
- bilateral tubal occlusion/ligation (can be via hysteroscopy [an endoscope accesses the uterus/fallopian tubes via the cervix], provided a hysterosalpingogram [an x-ray to look at the fallopian tubes and uterus] confirms success of the procedure)
- intrauterine device (IUD)
- intrauterine hormone-releasing system (IUS)
- vasectomized sexual partner(s) (provided the vasectomized partner has received medical assessment of the surgical success and is the sole sexual partner of the trial participant)
- true abstinence: refraining from heterosexual intercourse when this is in line with the preferred and usual lifestyle of the patient (periodic abstinence [e.g., calendar, ovulation, symptothermal, post-ovulation methods] and withdrawal are not acceptable).
- male or female condom with or without spermicide OR cap, diaphragm or sponge with spermicide should be used in addition to one of the birth control methods listed above (excluding true abstinence).

Some methods of birth control will not work when you are taking certain drugs. If you decide to take part in this study and you are able to become pregnant, a pregnancy test will be done before your participation in the study and regularly at some trial visits and at the end of the trial.

Once you're enrolled in the study, if you become pregnant or think you could be pregnant or are trying to get pregnant, it is important for you to tell the study doctor or staff immediately. If you become pregnant during the study, you will no longer receive study drug. Even if you are no longer in the study or not

receiving study drug, your study doctor will contact you about the outcome of the pregnancy including following the birth of an infant to find out about the baby´s health.

You may take part in this clinical study if you are surgically sterilized (both ovaries or fallopian tubes removed, or uterus removed) or you are post-menopausal (no menses for at least 1 year without other cause identified), although a blood test may be required to document that you are post-menopausal.

Risks Related to Study Procedures:

- Blood testing: Blood draws may cause pain, bleeding, and/or bruising where the needle is inserted in your vein. You may feel faint or pass out. There is a risk of bleeding or bruising at the puncture site and/or development of a small scar or an infection with redness and irritation of the vein at the site where blood is drawn. Although the amount may vary slightly at each visit, a total of approximately 239mL (16 Tbs or slightly less than 1 Cup) will be drawn during the study.
- Subcutaneous injection of risankizumab or placebo: a needle is used to inject the study drug or placebo under the skin. This can cause skin irritation and/or itching.
- Electrocardiogram (ECG): Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used. To do the ECG, you will have pads placed on different parts of your body. There is no pain or discomfort during an ECG; however, removing the pads may cause some irritation to your skin (itching and/or redness).
- Physical Exam: there are no special risks with an exam. It will be like examinations you have had in your doctor's office in the past.
- PPD test (to test for TB infection): there may be slight discomfort where the SC injection is administered. Rarely, people can have a larger skin reaction at the site. Depending on your symptoms, this may require treatment for a couple of days.
- Rescue Medication: You should ask the study doctor or study staff about the risks of using rescue medication.
- Stopping Medication(s): If you stop or change the dose of your regular medication, therapy, or supplement to be in the study, your PsA symptoms might come back or get worse or your health might get worse. Please tell the study doctor or study staff right away if you have any problems when you stop or change your regular medication, therapy, or supplement.
- X-ray of hands and/or feet (if applicable): there can be small risks of radiation from the X-ray.
- Questionnaires/Surveys: You may feel uncomfortable or embarrassed by some of the questions asked regarding how your psoriatic arthritis affects your daily activities. You may feel burdened by the need to complete questionnaires at each visit.

Please ask the study doctor or study staff if you have questions about the risks of the study procedures. In addition to your study doctor's research team and the Sponsor's Medical Monitor for safety in this study, an external independent committee will be reviewing subject safety. If this group finds that the

safety of the study participants or the study drug is a concern, your study doctor and the Sponsor will be informed and possibly the study halted.

Unknown Risks:
You may experience side effects that are not listed in this informed consent. As with any investigational drug, administration of risankizumab may involve risks that are currently unknown, including life threatening reactions or the remote possibility of death.

You should notify the study doctor of any changes in your health or new symptoms you are experiencing, even if you think these changes are not related to study drug.

The research study team will tell you in a timely manner if information is learned that could change your mind about continuing in this research study. Your decision will not affect the medical care you receive.

Please keep in mind how the study tests and visits described here will affect your work and family schedules. Consider if you need transportation to and from the clinic. You may find that these visits need some planning. Let a study team member know if you have any questions about the tests and procedures for the study.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. 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.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?
You may or may not benefit from being in this study but your participation in this research study may benefit future patients with your disease or condition. Your condition may get better, it may get worse, or it may stay the same.

IS THERE COMPENSATION FOR MY TIME AND/OR TRAVEL?
Compensation is given for each completed study visit. You will receive $75.00 for your participation after each study visit, up to an estimated maximum of $2,175. A check from the research foundation, [redacted] will be mailed to your home or P.O. Box address. Any payment for taking part in a research study may be considered taxable income. [redacted] will have to report this to the Internal Revenue Service (IRS) and will require your Social Security Number. This will be reported using a 1099 (Miscellaneous Income) form. This form will be issued to you and a copy will be sent to the IRS.

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Principal Investigator: [redacted] MD VA Facility: [redacted]

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?
You are being invited to participate in this study because DMARD treatment has not worked well for you or you were not able to tolerate DMARD treatment well. In addition to DMARD treatments, there are biological medicines that are approved to treat psoriatic arthritis. Some over-the counter nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen have been known to help reduce inflammation, pain and swelling. You may discuss these options with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?
Your name/identity will not appear in any publication or presentation of the data. Your medical records will be kept confidential as described in this form and as allowed by the applicable laws. A Category II (Research) flag will be placed in your Computerized Patient Record. The flag alerts medical and research personnel to your participation in this study. The Privacy Officer [redacted] can be contacted for additional information.

To help answer the research questions, the study doctor and research team will use and store personal health information about you as explained in the HIPAA section below. We will only share your personal health information as described below or if required by law.

Who will see my protected health information?
The study doctor and the research team will use your personal health information to carry out this study. By signing this consent, you allow access to your personal health information (including direct access to your medical records at the study site or any other facility where the study is conducted) to the following:

Who may have access:	**Purpose:**
The sponsor and its representatives	To oversee the study and make sure the information is correct
The study doctor and the research team	To conduct the study and make sure the study information is correct
The FDA and government agencies that regular research in the US and other countries	To make sure applicable laws are being followed
[redacted] IRB	To protect the rights and safety of subjects and make sure applicable laws are followed

Except when required by law, any information about you that is sent outside the research site will be assigned a numerical code. This code replaces your name, address and other information that can identify you. The Sponsor and people and companies working with the sponsor will have access to and use these coded records and samples and accompanying data to conduct the research described in this form. However, they will not be able to see the key that links the code to you. We will keep your personal health information as confidential as possible. It is not likely your personal information will be given to others without your permission.

The blood and urine samples that we collect from you will be stored, processed, and used as described in this document. All blood and urine samples collected under this protocol will either be processed and analyzed locally [redacted] or sent to [redacted] Unless otherwise specified, samples will be destroyed once all required tests and analyses are completed. AbbVie will not sell your biological samples to other people or companies. All biological samples collected from you will be given a unique code, as described above, to protect your confidentiality. In addition, in the "Do I Have to Take Part in the Study" section, you can find information about what to do if you no longer want AbbVie to use your biological samples

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.

While this study is being conducted, you will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, HIV status, drug, or alcohol treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include [redacted]; the study sponsor AbbVie Inc. and their compliance and safety monitors; [redacted] for analysis of your specimens; [redacted] Institutional Review Board, Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Department of Veterans Affairs

RESEARCH CONSENT FORM

Version Date: 02/12/2020

Participant Name: _____ Date: _____
Last, First, MI Suffix

Title of Study: M16-011: A Phase 3, Randomized, Double-Blind, Study Comparing Risankizumab to Placebo in Subjects with Active Psoriatic Arthritis (PsA) Who Have a History of Inadequate Response to or Intolerance to at Least One Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy

Principal Investigator: [redacted] MD VA Facility: [redacted]

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [redacted] MD and [redacted] research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?
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.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
Side effects or harm are possible in any research program despite the use of high standards of care and could occur through no fault of yours or the investigator involved. Known side effects have been described in this consent form. However, unforeseeable harm also may occur and require care. You do not give up any of your legal rights by signing this form. If you require or are billed for medical care that you feel has been caused by the research, you should contact the Principal Investigator, [redacted]

The VA must provide necessary medical treatment to any research subject injured by participation in a research project provided you have followed the directions of the study doctor and study staff. The research study will not pay for patient care that is not part of the research.

In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor at [redacted] during the day or [redacted] after business hours. If you need emergency hospitalization in a private hospital because you are unable to come to the VA, have a family member or friend contact your study doctor so that the VA can coordinate care with the private hospital. Emergency and ongoing medical treatment will be provided as needed.

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Principal Investigator: [redacted] MD VA Facility: [redacted]

DO I HAVE TO TAKE PART IN THE STUDY?
Participation in this study is voluntary. You may withdraw from the study at any time. All information that has already been collected for study purposes may continue to be used. You may be asked to complete a withdrawal clinic visit, but after that visit no further information about your health will be collected. There is no penalty or loss of benefits if you don't want to participate or withdraw your participation and your decision won't affect your regular medical care. There should be no adverse consequences to your health and welfare if you withdraw, and the study doctor will work with your primary care provider regarding any follow-up recommendations for treatment of your PsA.

If you sign this consent form, we will ask you for the names and contact information of some of your family members, friends, and/or your doctor(s) and for your permission to contact them if we are not able to contact you during your participation in the study, or after you may have withdrawn from the study, for important safety follow-up information.

Any information that can be found in the public (like a newspaper article or obituary) may be used for the study, even after you withdraw consent. If you are a VA employee, refusal to take part in this study will in no way influence your employment, ratings, subsequent recommendations.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION
The study doctor could, under certain circumstances withdraw you from participation without your consent for safety reasons (e.g. abnormal laboratory values) or for not complying with study procedures or visits. You may be asked to have a Withdrawal Visit and a Follow-up telephone call.

The study may be stopped early by the sponsor AbbVie, your study doctor, the [redacted] Institutional Review Board (IRB), or the FDA. You could be withdrawn from the study without your consent at any time and for any reason.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?
If you have questions about your research appointments, you may call the research coordinator.

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 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 Administrative Officer or the Research Compliance Officer at [redacted] if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

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Principal Investigator: [redacted] MD VA Facility: [redacted]

Contact	Phone or email
Emergency Contact Information	*Contact PI during the day (see below).* After hours call: [redacted]
PI: [redacted]	[redacted]
Project Manager or Coordinator	[redacted]
[redacted] Research Administrative Officer	[redacted]
Research Compliance Officer	[redacted]
Privacy Officer	[redacted]
IRB Office	[redacted]

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?
New information developed during the course of this study which may affect your willingness to continue in this research project will be given to you as it becomes available.

WHO COULD PROFIT FROM THE STUDY RESULTS?
If a possible commercial product will be developed in the future as part of this research, you will not profit from any products or tests that might result based on research with your specimens.

DOES THIS STUDY INVOLVE GENETIC RESEARCH?
No

HOW WILL MY GENETIC INFORMATION BE PROTECTED?
No genetic testing is being done at this site.

FUTURE USE OF DATA AND RE-CONTACT
It is possible that the Sponsor, AbbVie, will use your coded data for future research relating to the study drug, or psoriatic arthritis, or other similar diseases and medical conditions. Unless required by law or to obtain or dispense important safety information, we do not anticipate that we will need to contact you after the study has completed. You, however, will be free to contact the study doctor or any member of her team regarding any available information about your study participation or the study drug.

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Principal Investigator: [redacted] MD VA Facility: [redacted]

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms. _____ has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.		
Participant's Printed Name	Participant's Signature	Date
Presenter's Printed Name	Presenter's Signature	Date

Department of Veterans Affairs

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Version Date: 02/12/2020

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Principal Investigator: [redacted] MD VA Facility: [redacted]

Study Activities Table (Baseline to End of Study Follow-Up); W= week, D= day, PD= Post (after) Last Dose, F/U= follow-up

	Baseline	W4	W8	W12	W16	W24	W28	W32	W36	W40	W52 to W208 (every 12W)	Completion or PD (12W after last dose)	F/U Call 20W after last dose
Activity	D1	D28	D56	D84	D112	D168	D196	D224	D252	D280	D364 to D1456	D1540	D1596
Eligibility criteria reviewed	√												
Medical history update	√												
Medications update	√	√	√	√	√	√	√	√	√	√	√	√	√
Electronic questionnaires	√	√		√	√	√	√	√	√	√	√	√	
Health resource utilization (other medical visits)	√	√	√	√	√	√	√	√	√	√	√	√	√
Weight[a]						√					√	√	
Vital signs (blood pressure, pulse)	√	√	√	√	√	√	√	√	√	√	√	√	
Physical exam (annually after W52 and PD)	√					√					√	√	
Adverse events assessment	√	√	√	√	√	√	√	√	√	√	√	√	√
Physician/investigator assessments (varies)	√	√	√	√	√	√	√	√	√	√	√	√	
X-rays of your hands and feet[b]					√	√					√		
Urine pregnancy test (if applicable)	√	√	√	√	√	√	√	√	√	√	√	√	
Blood draw (tests performed vary at each visit)	√	√	√	√	√	√	√	√	√	√	√	√	
Joint tenderness and swelling assessments				√	√			√	√	√	√		
Randomization/drug assignment	√												
Administer study drug	√	√			√	√	√			√	√		
Anaphylaxis monitoring[c]	√	√			√	√	√			√	√		

[a]Weight is measured at W24, W52 and every 24 weeks thereafter. [b]Required at W16 if you are not responding to the study medication. Required at W24, W52 and W100.
[c]All subjects will be closely monitored for approximately 2 hours after the first dose administration (Study Day 1) and Week 24, and for 1 hour after all other dose administrations.