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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	A Phase 1/2 Study of Repeat Intra-Articular Administration of tgAAC94, a Recombinant Adeno-Associated Vector Containing the TNFR:Fc Fusion Gene, in Inflammatory Arthritis Subjects with and without Concurrent TNF-alpha Antagonists
PROTOCOL NO.:	13G01 WIRB® Protocol #20051203
SPONSOR:	Targeted Genetics Corporation Seattle, Washington United States
INVESTIGATOR:	Robert G. Trapp, M.D. 2528 Farragut Drive Springfield, Illinois 62704 United States
SITE(S):	The Arthritis Center 2528 Farragut Drive Springfield, Illinois 62704 United States
STUDY-RELATED PHONE NUMBER(S):	Robert G. Trapp, M.D. 217-546-6888 (24 Hours)

Introduction

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

You are being asked to take part in the clinical research study named above because you have inflammatory arthritis (pain and swelling of the joints - rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis). You have the right to know about the procedures, risks, hazards, discomforts, and possible benefits of this study to help you make an informed decision about whether or not you will volunteer to participate in the study. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

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Your participation in this research study is voluntary. You are free to withdraw your consent to participate or may refuse to participate at any time. This means that you can stop participation or refuse to participate for any reason, without penalty or loss of benefits that you are otherwise entitled to. Withdrawal or refusal will not affect your medical care or other available treatments for your inflammatory arthritis. If you withdraw or refuse to participate, it will not affect your participation in other clinical studies.

About 120 volunteers will take part in this clinical research study. The study is taking place at research sites in the United States.

Purpose of this study

The purpose of this study is to find out if repeat injections of the investigational gene transfer agent tgAAC94 (study agent) to a single joint are safe. An investigational agent is one which has not been approved by the U.S. Food and Drug Administration (FDA). It is not known if gene transfer will work in people with inflammatory arthritis. In this study tgAAC94 will be given to subjects who do and do not also use approved TNF-α blockers such as etanercept (Enbrel®), infliximab (Remicade®) and adalimumab (Humira®).

Study Agent

Gene transfer is an experimental procedure that introduces a gene coding for a protein directly into cells in the body. The body can then use the gene to make the protein. However, genes cannot be introduced inside the cell without help. In the case of tgAAC94, a small and simple virus called adeno-associated virus (AAV) has been modified to contain the gene coding for the TNFR:Fc protein, which is the same as the medication called etanercept or Enbrel®. However, Enbrel® does not contain the gene, only the protein. AAV infects many people in everyday life, but does not cause disease in humans. Although tgAAC94 was modified from AAV, tgAAC94 cannot grow in your body because all the AAV genes, including those that it needs to grow, have been removed.

By injecting tgAAC94 directly into an affected joint in your body (called the target joint), we hope it will help the body make a protein that stops the inflammatory process and reduces the progressive joint destruction and resulting disabilities associated with inflammatory arthritis.

Selection of study subjects

- You must not have tested positive for HIV, tuberculosis (unless adequately treated), hepatitis B or hepatitis C.
- If you are a female, you must not be pregnant or breast-feeding and you must be willing to practice effective birth control measures during your participation in the study.
- If you are a male, you should not father a child and you must be willing to practice effective birth control measures during your participation in the study.
- There may be other reasons you may not participate in the study. Your study doctor will discuss these reasons with you.

Study Setup

The study is divided into six groups called "cohorts". The dosage of study agent you receive will depend on which cohort you are in. The first three cohorts are known as "dose-escalation." This means that subjects enrolled into the second cohort will receive a higher dosage of study agent than subjects enrolled into the first cohort, and subjects enrolled in the third cohort will receive a higher dosage of study agent than subjects enrolled into the second cohort. Cohorts four, five and six will be enrolled simultaneously (at the same time). Subjects enrolled in cohort four will receive the same dosage as subjects in cohort one. Subjects enrolled in cohort five will receive the same dosage as subjects in cohort two. Subjects in cohort six will receive the same dosage as subjects in cohort three. Each of the six cohorts will have 20 subjects and will be divided into two parts: Segment A and Segment B.

If you qualify for the study at screening and wish to participate, your research doctor will determine which eligible joint (knee, ankle, elbow, wrist or knuckle) will be targeted for injection. In Segment A, you will be randomly (by chance) assigned to receive either study agent or placebo. The placebo looks like the study agent, but does not contain tgAAC94. There is a three out of four chance that you will get the study agent and a one out of four chance that you will get the placebo. Segment A is called "double-blind". This means that neither you nor the research doctors and nurses will know if you have been given the study agent or the placebo.

Information about whether you receive study agent or placebo will be kept secret (blinded) in a locked file at Targeted Genetics Corporation. In a medical emergency, this information may be revealed (unblinded) to the research doctor to make decisions about your medical care. It may also be revealed to the Data Monitoring Committee, which is an external group that oversees the research study.

Once your research doctor determines that you are eligible to receive a second injection (no sooner than 12 weeks after receiving your first injection but no longer than 30 weeks), you will be enrolled into Segment B of the study. Segment B is called "open-label", which means you and the research doctors and nurses know that you will receive study agent. In Segment B, you will receive an injection of study agent at the same dose concentration as the first injection for your cohort. The injection will be given in the same joint that was injected in Segment A.

How long will the study last?

The screening process may take up to two weeks. Segment A of the study may last between 12 and 30 weeks depending on when you become eligible to receive a second injection. Segment B will last about 30 weeks. Including screening, the total length of your participation will be between 44 and 62 weeks (10 and 15 months). The total number of study visits may range from 14 to 16.

Study Procedures

If you agree to participate, you will sign this informed consent form. You will be given a copy of this consent form to keep. The original will be kept by your research doctor.

Day -14 (Screening)

- You will sign the informed consent form, (if not already done).
- You will have a medical examination, including physical exam and vital signs (vital signs are pulse, breathing rate, blood pressure and temperature), and be asked questions about your general health and any medications you currently take or have taken in the past four weeks.
- Your study doctor will examine your eligible joints and determine which joint is to be injected.
- You will be asked to provide a blood sample (about 2 to 3 tablespoons).
- You will be asked to provide a urine specimen.
- You will have a PPD test (a test to see if you have been exposed to tuberculosis). If it is positive you may need to have additional tests to confirm whether or not you have active tuberculosis. If you do, it will have to be reported as required by law.
- You will have an electrocardiogram: (ECG or EKG - tracing of the electrical activity of the heart) and a chest x-ray.
- If you are a woman capable of becoming pregnant, you must have a urine pregnancy test.

Study Visit Schedule

If you qualify at screening, you will be asked to return to the research clinic within 14 days to be injected with either study agent or placebo (Segment A - Day 0). You will then be asked to complete additional study visits based on the following schedule:

Study Visit/ Segment	Day 0	Day 3	Day 7	Week 4	Week 8	Week 12	Week 18	Week 24	Week 30	USV	EW
Segment A	X	•	X	X	X	X	X	X	X	USV	EW
Segment B	X	•	X	X	X	X	X	X	X	USV	EW

X = Study visit is required
X = Study visit is not necessary if target joint is eligible for second injection at or before that visit.
• = Phone contact.
USV = Unscheduled Visit: only required to assess possible injection site reaction or worsening of target joint.
EW = Early Withdrawal visit: only required if study participation is stopped early after receiving an injection.

At each study visit (during both Segment A and B) the following procedures will be conducted:

Day 0 (Injection Visit)

- You will have a medical examination, including physical exam and vital signs, and be asked questions about your general health and any changes in medications since your previous study visit.
- Your research doctor will examine the target joint.
- You will be asked to provide a blood sample (about 2 to 3 tablespoons).
- You will be asked to provide a urine specimen.
- You will complete questionnaires about your overall disease activity, pain and disability associated with your inflammatory arthritis (if you have ankylosing spondylitis, you will also be asked to complete the Bath Ankylosing Spondylitis Functional Index and the Bath Ankylosing Spondylitis Disease Activity Index).
- Your research doctor will conduct a count of your tender and swollen joints and complete a global assessment of your inflammatory arthritis.
- Your height and weight will be measured.
- If you are a woman you will have a urine pregnancy test.
- If fluid is present in your target joint, your research doctor will remove the fluid (if possible) with a needle and syringe.
- You will have your target joint injected (with study agent or placebo if Segment A; with study agent if Segment B).
- After your target joint is injected, you will be asked to remain in the clinic for one hour to monitor you for any side effects.

About three days after completing the Day 0 (injection) visit, you will be contacted by your research doctor, or designated research personnel, and asked questions about your general health and any changes in medications since your injection. If you have symptoms (like increased swelling of the injected joint) that sound like an injection site reaction, you will be asked to return to the research site for an unscheduled visit.

Day 7

- You will have a medical examination, including physical exam and vital signs, and be asked questions about your general health and any changes in medications since your previous study visit.
- Your research doctor will examine the target joint.
- You will be asked to provide a blood sample (about 2 teaspoons), if Segment A and you are one of the first ten subjects enrolled in cohorts two or three.
- You will complete a global, pain and disability assessment of your inflammatory arthritis if you are enrolled in cohorts four, five or six.

Week 4, Week 8, Week 12, Week 18, Week 24, and Week 30

- You will have a medical examination, including physical exam and vital signs, and be asked questions about your general health and any changes in medications since your previous study visit.
- Your research doctor will examine the target joint.
- You will be asked to provide a blood sample (about 2 to 3 tablespoons).
- You will complete a global, pain and disability assessment of your inflammatory arthritis (if you have ankylosing spondylitis, you will also be asked to complete the Bath Ankylosing Spondylitis Functional Index and the Bath Ankylosing Spondylitis Disease Activity Index).
- Your research doctor will conduct a count of your tender and swollen joints and complete a global assessment of your inflammatory arthritis.
- If fluid is present in your target joint, your research doctor will remove the fluid (if possible) with a needle and syringe. (Week 4, Week 12 and Week 24 only).
- You will be asked to provide a urine specimen (Week 4 and Week 30 only).
- You will be weighed (Week 12, Week 24 and Week 30 only).
- If you are a woman capable of becoming pregnant, you will have a blood or urine pregnancy test (Week 30 only).
- You will have a chest x-ray (Week 30 only).

At the Week 12, Week 18, and Week 24 visits of Segment A, your research doctor will examine your target joint and decide if it is eligible for the second injection. If so, the remaining procedures for that visit will not be performed, and you will be asked to return for the Day 0 visit of Segment B within 14 days to have the second injection, which will be study agent (tgAAC94). If your target joint does not become eligible for a second injection prior to Week 30 of Segment A, you will automatically switch to Segment B and receive the second injection at the week 30 visit.

Unscheduled Visits

You may be asked to return for an unscheduled visit if you develop symptoms that sound like an injection site reaction or flare (worsening) of the target joint. If so, the following procedures will be performed:

- You will have a medical examination, including physical exam and vital signs, and be asked questions about your general health and any changes in medications since your previous study visit.
- You will be weighed
- Your research doctor will examine the target joint.
- Your research doctor will conduct a count of your tender and swollen joints.

If your research doctor determines that you have a flare of the target joint and are eligible for a second injection, you will be asked to return for the Day 0 visit of Segment B within 14 days. If your research doctor determines that you have a possible injection site reaction, the following procedures will be performed at the unscheduled visit:

- You will be asked to provide a blood sample (about 2 to 3 tablespoons).
- You will complete a global, pain and disability assessment of your inflammatory arthritis if you are enrolled in cohorts four, five or six.
- If fluid is present in your target joint, your research doctor will remove the fluid (if possible) with a needle and syringe.

If your research doctor suspects that you have an injection site reaction at a regularly-scheduled visit, the above evaluations will be performed, if they are not already part of that study visit.

Long-Term Follow-up

This study involves gene transfer. The U.S. federal government has established strict requirements for gene transfer studies. One of the requirements is that if you receive tgAAC94, you will be expected to cooperate in long-term follow-up after study agent administration. Long-term follow-up after the last injection of study agent will consist of annual contact by telephone for two years. You will be asked to provide a list of persons to contact in case you cannot be reached. If you move, you will be asked to provide your new address and telephone number to your research doctor. Your research doctor or a member of his/her staff will contact you once a year by telephone during the two-year follow-up to ask questions about any hospitalizations and new medical conditions you may have had. This is important to determine if there are any long-term consequences of receiving a gene transfer agent.

To fully evaluate the effects and safety of gene transfer, it is necessary to obtain as much information as possible. If you die, no matter what the cause, evaluating your organs by autopsy might be very helpful in understanding the full effects of gene transfer, if there are any. In order to comply with the National Institutes of Health (NIH) requirements of gene transfer studies, if your research doctor learns of your death within 24 hours of the event, then an autopsy will be requested from your family or next-of-kin. By participating in this study, you are granting your research doctor permission to make this request of your family, but this does not mean that you are giving permission for an autopsy. However, you are encouraged to discuss this with your family in advance.

Risks, Hazards and Discomforts

Risks Associated with tgAAC94 (study agent)

The risks associated with tgAAC94 can be divided into (1) the risks associated with the gene that is transferred to the body and the protein for which it codes, and (2) the risks associated with the AAV used to introduce the gene into the body.

The gene that is transferred to the body codes for a protein that is the same as the approved medication called etanercept or Enbrel®. Etanercept has been given by an injection under the skin to many people with inflammatory arthritis with remarkable improvement in their symptoms. It has been given directly into the joint of a small number of people with inflammatory arthritis with some improvement in the symptoms, but in one case, there was increased swelling of the joint. It is not known if the risks of giving the gene coding for the protein directly into the joint will be the same as giving etanercept itself. The risk of giving injections of tgAAC94 into the joints of people who are taking other TNF blockers like infliximab, (Remicade®) and adalimumab (Humira®) is unknown.

Side effects (or negative symptoms) associated with injection of etanercept under the skin include serious bacterial infections, especially if you also have diabetes, reactivation of tuberculosis, demyelinating symptoms (like those associated with multiple sclerosis) and lupus-like reactions. These serious adverse (bad or harmful) effects occur in about 10% of patients who receive etanercept. Other reported side effects are seizures, inflammation of the nerves, fever, bruising, serious blood disorders and paleness. These side effects could be possible with the use of tgAAC94.

Targeted Genetics Corporation has used AAV to introduce genes into over 220 people. These included about 140 subjects with a genetic disorder called cystic fibrosis (CF) who received doses of a similar AAV vector into the nose, maxillary sinus and lung, and about 65 healthy volunteers who received an injection of a similar vector into the muscle in an HIV vaccine study. Some subjects administered the highest doses developed an immune response. This immune response consisted of elevated proteins that interact with AAV in the blood. No side effects related to the development of this immune response have been noted so far. We do not know if the same immune response will develop after injection of tgAAC94. It is possible that this type of immune response will make additional injections of tgAAC94 or other AAV vectors in the future difficult or impossible.

A single dose of tgAAC94 has been injected into the joints of both rats and monkeys without raising any safety concerns. A single dose of a different AAV vector, containing the rat version of TNFR:Fc, has also been injected into the joints of rats with arthritis without causing any problems. The arthritis in these rats seemed to improve. A single injection of tgAAC94 has been given to the joint of approximately 10 humans in another study of tgAAC94 without raising any safety concerns.

Repeat injections of tgAAC94 into joints have been given to rats once a month for three months. After the second injection of tgAAC94, approximately 20% of the rats developed mild swelling in the joint that resolved after a few days. It is possible that you may develop increased swelling of the joint after you receive the second dose of tgAAC94. If the swelling is severe, you may be treated with an injection of steroid into the joint to help reduce the symptoms. However, if you receive an injection of steroids into the target joint, you will be withdrawn from the study.

Another possible consequence is that tgAAC94 could spread to other parts of your body. The risks of this are not known at this time. We have seen this type of spread in animal studies when tgAAC94 has been given by injection into the joint.

There is a very small chance that the tgAAC94 could damage the DNA in the cells of your body by inserting itself into your genes. If this happened, it could put you at risk for developing cancer in the future.

The U.S. Food and Drug Administration (FDA), which oversees clinical studies of investigational drugs in the United States, was made aware of an animal study where a number of newborn diseased mice injected with very high doses of an AAV vector developed liver tumors. This was a research study using an AAV vector that was not designed or produced for human use. The vector used for the mouse study did not contain the TNFR:Fc gene and it was not designed to treat inflammatory arthritis. Tumors have not been observed in other similar studies of different types of mice injected with higher doses of AAV vectors and watched for over a year. There have been no reports of tumors in the limited number of human subjects who have received an AAV vector. Tumors have not been reported in any other animal studies of AAV vectors, but the number of studies that have been done so far is small. It seems unlikely that the tumors are linked to the AAV vector, but we do not know for sure.

Since we do not know what tgAAC94 will do to an embryo or fetus, females who might be able to become pregnant must not be pregnant while in the study. Any female of childbearing potential who joins the study will have a pregnancy test before she receives the tgAAC94 or placebo. Both males and females who join this study must agree to use effective birth-control during the entire study, as we do not know what the study agent could do to a developing baby. Effective forms of birth control include hormonal therapies (for example, the pill), barrier methods (for example, condoms with spermicide), IUD, surgically sterility (for example, a hysterectomy or vasectomy) or menopause (for at least one year). If you become pregnant, suspect that you became pregnant, or impregnate someone while on the study, you must notify your research doctor immediately. If you are pregnant and are scheduled to receive study agent or placebo, you will be immediately withdrawn from the study.

There may be other not-yet-identified side effects that could occur during the time you participate in the study or years after receiving the study agent. Unknown side effects could be mild, serious or life threatening, and could result in pain, discomfort, disability or, in rare circumstances, death.

Risks and Discomforts Associated with Study Procedures

Blood samples are taken by putting a needle into your vein, which can cause pain, bruising, and, rarely, infection. Removal of fluid from the joint can also cause temporary local pain, bruising, and rarely, infection. As with any injection into the joint, subjects may experience pain, tenderness, redness, discoloration or bruising at the site of injection. The risk of infection is small, but you could get one from these procedures. You will receive a small amount of

radiation from the chest x-ray. However, this amount is too low to be measured directly and is considered to be comparable to receiving several weeks of natural background radiation exposure, which most people in the United States receive each year.

You will be watched and treated for any complications during and after the procedures. Your research doctor and nurses will monitor your disease status and check for side effects with blood tests and physical examinations.

Your condition may not get better or may become worse during this study.

Research studies involving gene transfer have received a great deal of attention from the media. Although every effort will be made to protect your identity and that of your family, this attention may result in a greater risk than usual that information concerning your study participation will appear publicly without your consent.

New Findings

You will be notified if there are any significant new side effects or information that might change your decision to be in the study.

Potential Benefits

We do not expect you to receive any direct medical benefit from participation in this study.

Because you are in this study, you will undergo more frequent monitoring of your inflammatory arthritis, which may give additional information to you and your research doctor about the progress of your disease. It is possible that this extra monitoring and testing could improve your health while you are in the study, but we do not know if this will happen.

The results of this study may give Targeted Genetics Corporation and the research doctors more information to use in the next step of developing a gene transfer agent for inflammatory arthritis.

Costs of the Study

Neither you nor your insurance company will be charged for any tests or procedures that are done for the purposes of the research study. Study agent will be provided without charge by Targeted Genetics Corporation, the sponsoring company.

You or your insurance company will be billed for costs of tests or procedures that are part of your routine medical care.

Compensation

You will not be paid for your participation in this study.

Alternative Therapy

An alternative to administration of the tgAAC94 or placebo is the current standard treatment available to patients with rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis at The Arthritis Center. Your research doctor will discuss this treatment with you during the consent process.

Voluntary Participation/Withdrawal

Your participation in this study is voluntary. You may choose not to participate or withdraw your consent to participate in this study without penalty or loss of benefits to which you are entitled. You should notify your research doctor as soon as possible if you decide to withdraw your consent. Your research doctor or Targeted Genetics Corporation may also decide to stop this clinical study for either medical or administrative reasons at any time and without your consent. This could happen if the research is not beneficial, an unexpected harmful side effect of the study agent is found or the study resources are no longer available.

If you discontinue the study early (after Day C but before Week 30 in either Segment) for any reason, you will be asked to return to the clinic for one or more safety checkups. The procedures and assessments completed at the Early Withdrawal visit will be the same as those that are completed for the Week 30 visit. Regardless of the reason for your discontinuing the study, clinical information relevant to this research study will continue to be collected. This includes information about study-related injuries and long-term follow-up.

If you develop a severe side effect, like increased swelling of your target joint that your research doctor thinks is due to the study drug, you may not qualify to receive the second injection of open-label study drug. In such a case, your research doctor will ask you to return for study visits until the time of the second injection (Week 30 of Segment A); then you will be withdrawn from the study. If you have already received a second injection of study drug and your research doctor thinks you have a severe side effect due to the study drug, you will be asked to complete the study through Week 30 of Segment B.

Compensation for Injury

If you are injured as a direct result of participating in this study, medical treatment for immediate complications will be provided to you without charge. This does not constitute a waiver of any rights you may have under federal or state laws and regulations.

Source of Funding

Funding for this research study will be provided by Targeted Genetics Corporation.

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AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The research doctor must get your authorization (permission) to use or give out any health information that might identify you.

What information may be used and given to others?
If you choose to be in this study, the research doctor will get personal information about you. This may include information that might identify you. The research doctor may also get information about your health including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about
  - Other reportable infectious diseases
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Questionnaires
- Records about any study agent you received

Who may use and give out information about you?
Information about your health may be used and given to others by the research doctor and staff. They might see the research information during and after the study.

Who might get this information?
Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. For this study, "sponsor" also includes AXIO Research Corporation, an agent for the sponsor.

Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- The Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by WIRB®. WIRB is a group of people who perform independent review of research as required by regulations.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the research doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Because the study involves gene transfer, safety information is required to be reported to the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health. No information by which you can be identified will be reported with the safety information. This safety information is available to the general public. In addition, the media (TV, newspaper, radio, Internet, etc.) may have an interest in the study. The Arthritis Center and Targeted Genetics Corporation will make every reasonable effort to protect your privacy and will not divulge private/specific medical information without your consent.

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End of Study

At the end of the study, the results will be analyzed. If you wish, your research doctor can tell you the results and whether you received the study agent or placebo as your first injection.

Questions

If at any time you have any questions related to the study, or if you believe you have experienced a research-related injury, you can contact:

Robert G. Trapp, M.D. at 217-546-6888 (24 Hours).

If you have any questions concerning your rights as a study subject, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: ClientServices@wirb.com

WIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, a copy of your signed and dated consent form will be given to you.

Consent

I have read this consent form, and all my questions have been answered. My signature indicates that I give my consent to participate in this study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Signature of Subject _____ Date _____

Printed Name of Subject _____

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The contents of this consent form were verbally presented to the subject and all questions were answered completely.

Signature of Witness (if required) — Date

Printed Name of Witness (if required)

Signature of Person Conducting Informed Consent Discussion — Date: 2/12/07

Printed Name of Person Conducting Informed Consent Discussion

(20 Jul 05)