Informed Consent Form
And
Authorization To Disclose Health Information

Sponsor / Study Title:	**The National Institute of Allergy and Infectious Diseases (NIAID) / "Evaluation of AMG 714 for Vitiligo: A Phase 2a Randomized Double Blind Placebo Controlled Trial"**
Protocol Number:	**ITN086AI**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

1. Is my participation voluntary?

Yes. It is entirely up to you to decide to join this experimental study. If you decide to join, we will ask you to sign and date this consent form and give you a copy to keep. You are free to leave the study at any time without having to give a reason. A decision not to take part or to leave the study at any time will, in no way, affect the care you receive.

2. Key Study Information

This consent form contains information that will help you decide whether or not to take part in this research study. We encourage you to read the entire document. All the information is important, but here are some key points to help you understand the study. Additional information is available in the consent form, in the sections noted in italics, below.

- This is a 12-month research study for people with vitiligo. *See Section 4, Introduction and Background and Section 5, Purpose of the Study.*
- The study will test if the experimental drug AMG 714 is effective in treating vitiligo by returning areas affected by vitiligo to normal skin color. An experimental drug is one that is not approved by the United States Food and Drug Administration (FDA). *See Section 5, Purpose of the Study.*
- The study may require up to 11 clinic visits and 1 telephone visit over 12 months of the study. *See Section 6.0, What makes up this study.*
- Study subjects have procedures that are not part of a routine doctor's visit. These include:
    - Completing questionnaires about vitiligo and personal well-being
    - Extra blood draws and skin biopsies
    - Skin photography. *See Section 6.0. What makes up this study.*

- AMG 714 has been tested in about 200 subjects with different diseases such as rheumatoid arthritis and celiac disease. AMG 714 is not approved for vitiligo. It has known side effects. The most common side effect is injection site reactions. As with all drugs, there can be other side effects that are not known. *See Section 7. Possible risks or side effects.*
- There might be no direct medical benefit to you for being in this study. The information learned from this study may someday benefit people with vitiligo. *See Section 8, Potential Benefits.*

3. Who is the study doctor?

The study doctor is listed as the "Principal Investigator (Study Doctor)" on page one of this consent form.

4. Introduction and Background

We invite you to participate in this study because you have vitiligo. Vitiligo is a skin disease. It is caused by the body's own immune cells attacking the cells in the skin that produce skin color, called melanocytes. The immune attack on the melanocytes in the skin causes the loss of your normal skin color and development of white spots on the skin. This can lead to a big change in a person's appearance. Vitiligo can affect people of any age, gender, or race. There are no FDA approved therapies for vitiligo. Common therapies used to reverse lost skin color include ultraviolet B (UVB) phototherapy and steroid cream, calcineurin inhibitor cream, and vitamin D cream. These therapies are often not effective. Research for therapies that are safe with few side effects that can produce long lasting results are needed.

In this experimental study, researchers will try to find out if AMG 714 can be safely used in people with vitiligo and if this therapy can bring back normal skin color in the white spots for people with vitiligo. AMG 714 may reduce your body's own over-active immune cells that are attacking the melanocytes in the skin that produce skin color. This would allow the melanocytes to produce normal color in the skin and white spots to disappear.

AMG 714 has been given to subjects with rheumatoid arthritis and celiac disease in experimental studies. It was generally found to be safe and well tolerated. However, the study results have not shown positive effects in studies of rheumatoid arthritis and celiac disease. AMG 714 has never been tested in people with vitiligo and its safety is unclear in this group of patients. AMG 714 has not been approved by the FDA to treat vitiligo.

5. What is the purpose of this study?

The main purpose of this study is to:

- Compare AMG 714 to AMG 714 placebo to learn if AMG 714 can be used safely in people with vitiligo
- Assess side effects
- Assess if AMG 714 can bring back the normal color to the skin

6. What makes up this study?

Who is sponsoring this study?
This study is sponsored by the National Institutes of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). It is being conducted by the Immune Tolerance Network (ITN).

How many people will be in the study? How many centers will conduct this study?
About 57 people will be in this study at about 5 to 10 centers in the United States (US).

What am I being asked to do? How long will I be in the study?
You are being asked to take part in this study because you have vitiligo. There are three parts to this study:

- **Part 1** is the screening phase to see if you qualify for this study.
- **Part 2** is the study treatment phase. 38 study subjects will receive AMG 714 injections every two weeks for six doses, and 19 study subjects will receive AMG 714 placebo injections (an inactive substance that looks like the drug) every two weeks for six doses. The study treatment will be administered from Week 0 - Week 10.
- **Part 3** is the follow-up phase to see if your vitiligo gets better or gets worse after the study treatment.

The below table lists the study tests, procedures and study drug you will receive at each visit during the study.

Phase of Trial	Screening	Study Treatment						Follow-up				
Week		0	2	4	6	8	10	12	18	24	36	48
Visit	V-1	V0	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10
Physical exam and vital signs	X	X	X	X	X	X	X	X		X	X	X
AMG 714 or placebo		X	X	X	X	X	X					
nbUVB phototherapy[1]										X	X	X
Blood samples	X	X			X			X		X	X	X
Urine pregnancy test		X	X	X	X	X	X	X		X	X	X
Vitiligo assessments	X	X	X	X	X	X	X	X		X	X	X
Vitiligo questionnaires		X			X			X		X	X	X
Skin photography		X			X			X		X	X	X
Skin biopsies		X						X		X		X

[1] Subjects will undergo narrow band ultraviolet B (nbUVB) phototherapy if T-VASI does not improve by at least 25% at Week 24 compared to Week 0.

Screening Phase
Once you have signed and dated this consent form, you will have a screening visit to see if you qualify for the study. At the screening visit, you will have a physical exam and vital signs will be checked (blood pressure, heart rate, temperature and breathing rate). We will ask you

questions about your medical history, age, gender, and race. We will also ask you questions about the medications you are taking and any side effects you are having. We will take blood samples to check your overall health. About 2 tablespoons of blood may be taken for tests at this visit. You will have a blood pregnancy test if you are a female and can get pregnant. Tests will be run for serious infections such as HIV, tuberculosis, and hepatitis. The study doctor may be required by law to report the result of these tests to the local health authority. A skin test called PPD skin test may be done to screen for tuberculosis instead of a blood test, if the blood test result is uncertain. Your study doctor will tell you how you will be tested for tuberculosis.

Your doctor will assess your skin and calculate a score using a skin scoring method called Total Body Vitiligo Area Scoring Index (T-VASI) by looking at the total area of body sites with vitiligo and the number of white patches. Your doctor will also assess your facial skin and calculate a score using a skin scoring method called the Facial Vitiligo Area Scoring Index (F-VASI) by looking at the total area of your face with vitiligo and the number of white patches. Photographs of your vitiligo will be taken, including photographs of your face. These photographs will be used to document the progress of your vitiligo during the study.

The screening phase may last up to 28 days. The screening visit may take 2 hours.

Study Treatment Phase (Visits 0-5/Weeks 0-10)

If you qualify and decide to join the study, you will be assigned to 1 of 2 study groups for the study treatment phase. A computer randomly picks who will be in which study group. Neither you nor your study doctor will know which study group you are assigned to.

If you are assigned to study group 1, you will receive AMG 714 injections. If you are assigned to group 2, you will receive the AMG 714 placebo injections (an inactive substance that looks like the study drug).

AMG 714 and AMG 714 placebo will be given as a subcutaneous injection (a shot under your skin) by the study staff every 2 weeks for a total of 6 doses. Each dose will be split into two injections and will be given into 1 side of your abdomen, approximately 1 inch apart. The side of the abdomen that will get the injections will alternate for each dose. Your vital signs (blood pressure, pulse, temperature, and breathing rate) will be checked just before you receive the study injections and one hour after you receive the study injections.

Study visits during the study treatment phase will also involve checking your health and quality of life. The study staff will ask you about any medications you are taking or have taken since your last visit. They will also ask about any side effects you may be having. You will have a physical exam and vital signs will be checked (blood pressure, pulse, temperature, and breathing rate). In addition, blood samples will be taken to assess your general health and for research tests. We will collect about 9 tablespoons of blood at visit 0 and visit 3. You will have a urine pregnancy test at each study visit if you are a female and can get pregnant.

Skin samples called skin biopsies will be taken for research tests at visit 0. One sample of normal skin and one sample of skin affected by vitiligo will be collected. You will have one 4mm (size of a pencil eraser) punch biopsy for each required sample.

About 2-3 stitches will be used to close the wound. You may need to return to the study site between study visits to have the stitches removed.

Your study doctor will assess your skin and calculate a score called T-VASI by looking at the total area of body sites with vitiligo and the number of white patches at visits 0 and 3. Your study doctor will also assess your skin and calculate a score called F-VASI by looking at the total area of your face with vitiligo and the amount of white patches at each visit. Your study doctor will assess the extent of your vitiligo and calculate a score called VES at visits 0 and 3. Questionnaires about vitiligo and personal well-being will be done at visits 0 and 3. Photographs of your vitiligo will be taken, including photographs of your face. These photographs will be used to document the progress of your vitiligo during the study. Your study doctor will ask you to look at one photograph of your face that was taken before you started study drug treatment and ask you to compare how noticeable your vitiligo is at that visit. This questionnaire is called VNS and will be done at visit 3.

Study visit 0 and 3 may take 3 hours and the other study visits may take 2 hours.

***Follow-up Phase* (Visits 6-10/Weeks 12-48)**

After you complete the 6 study drug treatment visits, you will be asked to come to the clinic for 4 more visits for follow-up. **Visit 7/Week18 will be a telephone visit and therefore there will be no assessments or tests done at Visit 7**. The follow-up phase is to monitor any changes in your vitiligo status, to assess overall safety and quality of life, and to collect blood and skin samples for research tests. At each visit the study staff will ask you about any medications you are taking or have used since your last visit. You will have a physical exam and vital signs will be checked (blood pressure, pulse, temperature, and breathing rate).

During these visits the study staff will also collect blood samples to assess your general health and for research tests. We will collect approximately 9 tablespoons of blood at each visit. You will have a urine pregnancy test at each study visit if you are a female and can get pregnant. Skin samples called skin biopsies will be taken for research tests. One sample of normal skin will be collected at visit 6. One sample of skin affected by vitiligo will be collected at visits 6, 8 and 10.

Your study doctor will assess your skin and calculate a score called T-VASI by looking at the total area of body sites with vitiligo and the number of white patches at each visit. Your study doctor will also assess your skin and calculate a score called F-VASI by looking at the total area of your face with vitiligo and the number of white patches at each visit. Your study doctor will assess the extent of your vitiligo and calculate a score called VES at each of these visit.

Questionnaires about vitiligo and personal well-being will be done at each visit. Photographs of your vitiligo will be taken, including photographs of your face. These photographs will be used to document the progress of your vitiligo during the study. Your study doctor will ask you to look at one photograph of your face that was taken before you started treatment and ask you to compare how noticeable your vitiligo is at that visit. This questionnaire is called VNS and will be done at each visit. At visit 6, you will also be asked whether you think you received AMG 714 or placebo.

Each study visit may take 2 hours during this phase. You will be contacted at least once between each study visit to maintain contact with your study doctor.

You will be in the study for a total of 1 year if you finish all 3 phases of the study.

If your disease gets worse during the study, you can stop study treatment and receive other treatments for your disease. If your skin does not improve by at least 25% as measured by the T-VASI at week 24, you will receive narrow band UVB (nbUVB) phototherapy starting after week 24 and lasting through week 48. nbUVB phototherapy is usually given 3 times per week but can vary based on your skin type and level of vitiligo. nbUVB phototherapy can be given in your study doctor's clinic or in your home using a home-based nbUVB phototherapy unit. You must wear special goggles or sunglasses during this part of the study treatment. This eye protection is very important. Male subjects must shield their genitals during the study treatment. The decision of whether to have nbUVB phototherapy given in clinic or at home is up to you.

If you decide to have nbUVB phototherapy at home, you will be given a home-based UVB phototherapy unit to use until the end of the study and your study doctor will give you an information sheet with the study treatment instructions.

Extra or unplanned study visits

You may be asked to see your study doctor in-between the visits mentioned above if your study doctor believes that your disease may be getting worse. You will be asked to do some of the tests included in the visits during the study treatment phase. If you leave the study early, you will be asked to come back for one last study visit and do all assessments included in study visits during the follow-up phase. At this final visit, up to 9 tablespoons of blood might be taken

COVID-19 related plans

There are increased risks of COVID-19 exposure when you have to leave your home for a study visit. Your study doctor may contact you before each study visit to ask some questions related to your current health status and any known exposures to people with COVID-19 infection. If there are local restrictions that prevent you from coming to a study visit, there are plans in place to allow Visits 1, 2, 4 and 5 to be done remotely.

Medications you are allowed to take during this study

Besides the study drug or placebo, you may take oral vitamins, minerals and dietary supplements. You may use a mineral-based sunscreen with SPF 30 or higher. One course of prednisone (or similar corticosteroid) with highest daily dose of 30 mg per day for up to 2 weeks is allowed if needed. You may use one course of topical corticosteroids for up to 2 weeks, or one course of intra-articular corticosteroids. You may use inhaled and nasal corticosteroids if needed. You may use any camouflage makeup, except during nbUVB phototherapy treatments. You may also continue to take other drugs needed to manage any conditions you have unrelated to vitiligo (such as medicine for diabetes, high blood pressure or heart problems).

Medications you may not take during this study

You may not take any other medications that suppress your immune system, including, but not limited to corticosteroids (except those allowed in the section above) and calcineurin inhibitors such as pimecrolimus or tacrolimus. You may not use tanning beds. You may not use other agents that can cause skin depigmentation such as monobenzyl ether of hydroquinone. You may not use any experimental drug other than the study drug. You may not use nbUVB phototherapy for the first 24 weeks of the study. You also cannot have vaccines that contain live organisms (for example, measles, mumps, rubella, polio or flu mist) while you are in this study.

You should check with your study doctor before taking any new medications or things like herbal treatments that you can buy from a drug store.

7. What are the possible risks or side effects?

Study Drug Risks

AMG 714 Risks

AMG 714 may cause all, some, or none of the side effects listed below. These side effects can be mild but could also be serious, life-threatening or even result in death. You may also experience an allergic reaction that has not been seen before with AMG 714. In general, symptoms of an allergic reaction may include:

- Headache
- Rash
- Itching
- Flushing
- Swelling
- Shortness of breath
- Nausea
- Vomiting
- Severe allergic reactions that could be life-threatening can cause
    - Dizziness
    - Severe skin reactions
    - Difficulty breathing or swallowing
    - A decrease in blood pressure

As of 10 September 2018, approximately 256 people have received AMG 714 in research studies. Side effects that other people have had that are thought to have been caused by AMG 714 are:

- Very Common side effects (which may affect more than 1 person in 10): Injection site reaction. Symptoms of injection site reactions include redness, tenderness, pain, bruising, warmth, swelling, and/or itching at the injection site.

• Common side effects (which may affect between 1 and 10 people in every 100): Injection site rash, eczema (red, itchy, scaly rash).

The effect of AMG 714 on cancer risk, fertility, pregnancy, breast-feeding, children and older adults is not known. There may be other risks that are unknown to us now.

Placebo Risks

If you receive placebo (the inactive substance) as part of this study, your symptoms of vitiligo may not improve or may get worse.

Study Procedure Risks

Blood Draw Risks
Possible side effects from having blood drawn include dizziness, redness and swelling of the vein, pain, bruising, or bleeding from the site of the needle puncture. There is also a chance of infection. Given your condition and the amount of blood being drawn during the study, there is also a risk of developing anemia (low blood counts).

Injection Site Reactions
AMG 714 and AMG 714 placebo may cause swelling, red marks or lumps where injections are given. Your chance of getting an injection site reaction is greater than 10% (more than one out of 10 people).

Reproductive Risks
You should not get pregnant while you are in this study. If you are a woman who can get pregnant you must agree to use a type of birth control that works well. You will have to use an acceptable method of birth control while you are in this study until the end of study week 48. If you leave the study early, you must be on birth control for 16 weeks after the last dose of AMG 714/AMG 714 placebo.

PPD Skin Test Risks
Symptoms may include tenderness, swelling, or a rash at the site of the injections. Cold packs can be applied to the area to help with any tenderness or swelling from the injections.

Skin Biopsy Risks
You will be given an injection (a shot) of numbing medication prior to your skin biopsy. There is some mild, burning sensation accompanying the injection of the local numbing medicine. In rare cases, the numbing medicine may cause an allergic reaction which if untreated could be life-threatening. This numbing medicine is called Xylocaine (sometimes called Lidocaine) and will be mixed with epinephrine. If you know you are allergic to Xylocaine or epinephrine, you should tell the study doctor.

There may be minor bleeding right after the biopsy that can easily be controlled by applying pressure on the spot for a few minutes. Rarely, a bruise might form, and this eventually goes away by itself. In people who have trouble with blood-clotting, larger bruises or prolonged bleeding may occur. Your study doctor will discuss this with you on an individual basis.

Sometimes an infection may occur at the biopsy site. This can usually be treated with topical antibiotics. On rare occasion, oral antibiotics may be needed. An infection can be recognized by redness, soreness, and pus at the site. It generally starts 2 days or more after the procedure and does not clear up in another couple of days.

Skin biopsy sites heal in a variety of ways. Scars may change for years after the stitches are removed. It is possible that scars may be red for some time, or become raised, darker or lighter than the surrounding skin. You will most likely have a permanent scar of some kind and looking at your prior scars may give the best prediction of your long-term healing.

Ultraviolet B Phototherapy Risks
The following side effects may occur from nbUVB phototherapy:
Sunburn, dryness or itching of the skin, inflammation of the hair roots, or sunlight-induced rash. nbUVB may fail to improve or may worsen your vitiligo.

Questionnaire Risks
There is a low risk of feeling uncomfortable due to questions that may be sensitive in nature. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

Photography Risks
There is a low risk that your photographs could reveal your identity. Study representatives will have access to your photographs, and there is a very low risk that an unauthorized person outside of the study may access your photographs. The photographs will not be labeled with your name.

8. Are there benefits to taking part in this study?
Taking part in this study may or may not make your vitiligo better. If the study drug does not work, or if you are on placebo, you may not benefit. Information from this study may help doctors learn more about the treatment for vitiligo. This information could help future vitiligo patients.

9. What other choices do I have if I do not take part in this study?
Before you decide to take part in this study, your study doctor will talk with you about other options available to you. If you decide not to join the study, your study doctor can recommend other treatments. You do not need to participate in this study to be treated for your vitiligo.

10. What about new findings?
During your participation in this study, your study doctor will inform you of any new findings from this or other research that may affect your willingness to continue in this study.

11. May I leave this study at any time?
Yes, you may leave the study at any time. If you decide to leave the study, there is no penalty or loss of benefits in your routine medical care or any other benefit(s) that you would otherwise be entitled to receive.

In addition, you should consult with the study doctor listed on page one of this consent form who will discuss future treatment and procedures for your continued care when you are no longer in this study.

12. Can I be taken off this study without my consent?
You may be removed from the study without your consent at any time. Reasons why you may be removed from the study include, but are not limited to, the following:

- Your study doctor decides that it is best for you not to continue.
- You are unable to complete study tests.
- The study is stopped by the Institution, the Sponsor(s), or other health authorities.
- You become pregnant or plan to get pregnant during this study.
- You take medications that suppress your immune system.
- You have severe side effects from the study drug, AMG 714.

If you are removed from the study, your study doctor will notify you about treatment or procedures for your future care. You will be asked to come back for one more visit to have some end-of-study tests for your safety.

13. What about pregnancy and birth control?
You cannot participate in this study if you are pregnant, breastfeeding or planning to become pregnant while in the study.

Female subjects must either be sexually inactive by abstinence or use a medically acceptable form of birth control while in the study. Periodic abstinence and withdrawal are not acceptable methods of contraception. Abstinence must start two weeks prior to the first dose of study drug.

Acceptable forms of birth control include oral birth control pills (combined hormone or progestin alone), injectable or implantable progestogens, intrauterine devices, estrogen vaginal rings, male partner sterilization, or double barrier methods (e.g., condom and occlusive cap with spermicidal agent). If using male partner sterilization, records of sterilization should be provided.

Birth control must be used throughout the study starting at two weeks before the first dose of AMG 714/ AMG 714 placebo until visit 10/week 48. If you leave the study early, you must be on birth control for 16 weeks after the last dose of AMG 714/ AMG 714 placebo.

Even if you are on birth control, you will be given a pregnancy test before and during the study. You and the study doctor will discuss acceptable methods of birth control.

If you become pregnant while in this study, or if you think that you have become pregnant, you must contact your study doctor right away. If you are still receiving the study drug, your study doctor will stop your study drug. You will continue to be followed until the baby is born or the pregnancy is stopped. Information requested about the delivery shall include gestational age at delivery, birth weight, length, and head circumference, gender, appearance, pulse, grimace, activity, and respiration (APGAR) score at 1 minute, 5 minutes, and 24 hours after birth, if available and any birth defects.

Male subjects are not required to use birth control during treatment with AMG 714. However, you should let your female partner know that you are in this study. If your female partner becomes pregnant while you are in the study, you should inform your study doctor right away. Your partner's pregnancy outcome information will be collected if available, which will include the number of infants; gender, weight, length, and head circumference of each infant; any infant complications, medical problems or birth defects.

14. What will it cost me to be in the study?
The costs of all medications, tests and procedures described above that are required by the study will be paid for by NIAID through the ITN. You will be responsible for any expenses related to your routine clinical care. Please ask your study doctor about any expected added costs that you may incur. Insurance companies and other carriers sometimes refuse to pay the costs of study treatment when individuals are participating in research. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may lead to added costs to you or your insurance company.

15. Will I be paid for taking part this study?
«Compensation»

You will receive $50 for each study visit to cover travel and other expenses for taking part in this study. You will receive another $100 for each biopsy.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***["after each visit," "annually," "bi-weekly," etc.]***

16. What if I am injured during the study?
If you are injured or get sick while in this study, it is important to tell your study doctor listed on page one of this consent form.

Emergency medical treatment will be available to you. The study site will bill you or your insurance company in the normal way for the cost of such care. No payment or additional compensation is available to you for such injuries. There is no provision for medical care at no cost to you or monetary compensation from the study sponsor, the NIAID, NIH. You do not lose any legal rights by signing and dating this form.

17. Will I be tested for HIV?

Yes. You will be tested for HIV as part of the screening visit before you start in the study. If you are found to be HIV positive you will not be permitted to participate in the study. Your medical records will be kept confidential to the extent permitted by law. However, as mentioned earlier in this consent form, the study doctor may be required by law to report the result of this test to the local health authority.

18. Will my identity be kept private?

Your medical and research records will be confidential to the extent permitted by law. Every effort is made to keep your identity private. However, we cannot always guarantee complete confidentiality.

Medical and research records from this study will be reviewed by the United States agency funding this study (the National Institute of Allergy and Infectious Diseases), including its representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring or analyzing the study.
In addition, the U.S. Food and Drug Administration (FDA), or other health authorities, and pharmaceutical sponsor(s) and their commercial partners may review your medical and research records for regulatory purposes.

You will be identified by a study code, not your name. The key to the code is kept in a secured file at the study site. Personal data from your records will not be released without your permission. You will not be named in any publication about this study. After the study is completed, this study data may be placed in a central storage location. The purpose is to make study data available to other researchers. This data does not include traditional identifiers (for example, names, address, medical record #, etc.). Information from this study may be put into databases along with information from other studies. There are different kinds of databases; some are publicly accessible, and some are restricted. Anyone on the internet can access publicly accessible databases. Only researchers who apply and are approved can access restricted databases. Traditionally used identifying information about you (such as name, phone number, address) will NOT be included or shared with others.

Your privacy is important to us and we will use safety measures to protect your privacy. In spite of all the safety measures that we use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you share some genetic information with your children, parents, brothers, sisters, and other blood relatives.

Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.

While we will not use information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative).

It is also possible there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. There may also be other privacy risks that we have not foreseen.

Organizations that may look at and/or copy your medical records for research, quality assurance and data analysis include:

- the National Institute of Allergy and Infectious Diseases, (NIAID) sponsor of the research,
- NIAID representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring or analyzing the study.
- the U.S. Food and Drug Administration,
- other State and Local health authorities, and
- pharmaceutical or device companies(s) and their commercial partners may review your medical and research records for regulatory purposes.

As a NIH funded study, you are further protected through a policy that prevents the study doctor from releasing any sensitive information about you that may identify you. This does not prevent you or a family member from voluntarily releasing information about this research.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

With regard to the photographs of your vitiligo, including photographs of your face, digital copies will only be stored at the study site and will not be accessed by anyone other than study representatives without your consent. The digital photos will be stored on a password-protected computer.

19. Whom To Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser:
[redacted]

20. Will any of my samples, information/data be stored for future use and shared with others?

Stored Samples and Information:

If you agree, we will store your blood, skin biopsy samples and information in the central ITN repository located in the United States. The purpose is to make these samples and information available for future research which is not yet planned and to share the stored samples with other researchers.

Information about you, including your biospecimens, collected for this study may be shared with other researchers. It may also be used for other research studies. We will make sure that your identity cannot be linked to the information we share. We will not ask you for additional permission before sharing the information.

Your decision to allow samples and data to be stored and shared is separate from your decision to participate in this study. If you decide to allow storage, your samples and data may be stored for an unknown length of time but for a minimum of 10 years. Blood samples used for research tests can include analysis of deoxyribonucleic acid (DNA). The samples will be stored using a code and may be sent to be tested in outside labs. All data are kept confidential and people testing the DNA will not have any of your other traditional identifiers (for example, initials, birthdate, address etc.).

This study will not look at large chunks of your DNA (whole exome testing) nor all of your DNA at once (whole genome testing).

Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and **you will not share in this profit**.

The results of tests done on your stored samples will not be given to you or your study doctor. The results will not be put in your records and will not change your medical care. There will be no benefits to you from the storage of these samples and information. However, the use of your samples and information may help researchers learn more about your disease or help study the genetics related to your disease.

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading," every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research **will not include** whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

There may be risks in allowing the storage, sharing, or analysis of samples and information. For example, if future research is for genetic testing and because genetic information is unique to you there is a risk that someone using your sample could trace it back to you. Researchers are required to protect your privacy and to keep your information private to the extent permitted by the law. This does not occur all the time when information is shared with others.

If information resulting from analysis of your samples is shared publicly, it will not contain traditional identifiers (for example, your name, birthday etc.). The samples and information will not be sold; however, the results of the tests could lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

You can change your mind at any time during the study and ask to have your stored samples destroyed. This request should be made in writing to the study doctor. If your samples have not been used, they will be destroyed. If your samples have already been tested or shared before your request is made, the information from these tests will be used and cannot be destroyed.

Please indicate your response below:

I agree to the storage and sharing of samples (blood and skin samples) for genetic tests and sharing of information/data resulting from the analysis of my genetic tests not currently planned.

☐ **Yes** ☐ **No**

_____

Initials of Research Subject

I agree to the storage and sharing of samples (blood and skin samples) and sharing of information/data resulting from the analysis of my samples for other tests (not genetic) not currently planned.

☐ **Yes** ☐ **No**

_____

Initials of Research Subject

You have the option to consent to the use of your photographs in publications or presentations. Your eyes will be blacked out in any published or presented photo to prevent you from being identified. This is *optional*, and you can refuse and still participate in the study.

Photography Schedule	Week 0	Week 12	Week 24	Week 48	Week withdrawal

I agree to the use of my digital photographs in publications and/or presentations.

☐ **Yes** ☐ **No**

_____

Initials of Research Subject

21. SIGNATURE PAGE

Please sign and date below if you agree to take part in this study.

- **You have read the informed consent, and/or had it explained to you**
- **You were given the opportunity to ask questions about the information**
- **You voluntarily agree to take part in the study**

Research Subject's Name (Typed or printed)	**Research Subject's Signature**	**Date**

Signature of person explaining and obtaining the consent:

Name and Title (Typed or printed)	**Signature**	**Date**

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include

- Representatives of The National Institute of Allergy and Infectious Diseases (NIAID).
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.
- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of the Person Obtaining the Authorization

_____ _____
Signature of the Person Obtaining the Authorization Date