INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**The National Institute of Allergy and Infectious Diseases (NIAID) / "Combining a CD40L-Binding Protein (VIB4920) with a TNF-α Inhibitor for the Treatment of Inadequately Controlled Rheumatoid Arthritis"**
Protocol Number:	**ITN092AI**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Please read this form carefully. Take your time to ask the study doctor or study team as many questions about the study as you would like. The study doctor or study team can explain words or information that you do not understand. Reading this form and talking to the study doctor or study team may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

Taking part in this study is your decision and is completely voluntary. You may change your mind at any time. There will be no penalties or loss of benefits to which you are otherwise entitled if you do not want to take part in the study.

KEY INFORMATION
You are invited to take part in a research study. The purpose of this study is to see how a new study drug, VIB4920 affects rheumatoid arthritis (RA). VIB4920 is also known as dazodalibep or HZN-4920, but will be referred to in this study as VIB4920. The National Institute of Allergy and Infectious Diseases (NIAID) is sponsoring this research study. The Immune Tolerance Network (ITN) is conducting the study. Amgen, the pharmaceutical manufacturer of VIB4920, is providing the study drug. All the information in this form is important, but here are some key points to help you understand the study. Additional information is available later in the consent form, in the sections noted in italics, below.

- This is a 40-week research study. It is for people with moderate to severe rheumatoid arthritis (RA) who still have active disease despite treatment. (*See Background and Purpose)*
- The study will see if a new study drug called VIB4920 reduces the joint pain and swelling from RA. *(See What Will Happen During the Study*)

You will be randomly assigned to one of three groups:

- One group will continue to take their current TNF-inhibitor, e.g., etanercept, adalimumab, golimumab, certolizumab or a biosimilar product. Individuals in this group will also receive VIB4920.

- One group will continue to take their current TNF-inhibitor, e.g., etanercept, adalimumab, golimumab, certolizumab or a biosimilar product, while also receiving Placebo (a product that looks like VIB4920 but has no active drug in it).

In these two groups, the study doctor, study team and the participant will not know whether the participant is assigned to receive VIB4920 or placebo. This is known as double-blinding. However, in an emergency, the study doctor can get this information.

- The third group will discontinue their current TNF-inhibitor. Participants in this group will be assigned to receive VIB4920.

In this third group, the study team member who examines the joints and asks about RA disease activity will not know what study treatment the participant is taking. This is known as evaluator-blinding. The other study team members and the participant will know the participant has stopped the TNF-inhibitor and is taking VIB4920.

- The study includes 16 clinic visits over the 40 weeks of the study. *(See What Will Happen During the Study)*
- Study participants have procedures that are not part of a routine doctor's visit. These include:
  - Completing questionnaires about your RA.
  - Extra blood and urine collections.

  (See What Will Happen During the Study)
- VIB4920 infusions have risks. The full list of side effects and study risks is in the *Risks, Side Effects and/or Discomforts* Section.
- 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 RA. (*See Benefits)*

BACKGROUND AND PURPOSE

We are asking you to join this research study because you have moderately to severely active RA despite current treatment with a TNF-inhibitor.

RA is a chronic (persistent or long-lasting) disease affecting up to 1% of the population. This disease results when the body's own immune system attacks the body, especially the joints, resulting in joint pain, stiffness and swelling. RA can also affect the lungs, heart, eyes, and bones. Persistent joint inflammation can damage your joints, reduce your ability to work, interfere with taking care of your family, home, or yourself, and decrease your quality of life.

Treatment for RA usually involves drugs designed to block the immune system. Some drugs that are currently used to treat RA are called disease modifying anti-rheumatic drugs (DMARDs). Some examples of DMARDs are methotrexate, hydroxychloroquine, leflunomide, and sulfasalazine. Other drugs in this category are used to treat RA and are called biologics. Some examples of biologics are etanercept, adalimumab and related biosimilars. RA patients often require combinations of these drugs to slow down the disease.

The relief from these drugs may only last for a short time and they usually do not cure the disease. These drugs can cause serious side effects. One is lowering the immune system too much which can lead to infections. Therefore, research for a new effective treatment for RA is needed to keep the disease under better control, and perhaps avoid the need for life-long medications.

In this research study, we want to see if VIB4920 will improve the control of moderate to severe RA. VIB4920 is an experimental treatment. It has not been approved by the United States (U.S.) Food and Drug Administration (FDA) for use in RA or any other condition at this time.

VIB4920: VIB4920 is a man-made protein manufactured by Amgen. This protein works by blocking a pathway that allows certain cells of the immune system to attack one's own body parts such as the joints. Decreasing the amount of destructive immune cells may result in your RA becoming less active or even inactive. In one early study, VIB4920 decreased the joint pain and swelling of RA.

About 104 subjects will participate in this study at about 12-15 sites in the U.S.

WHAT WILL HAPPEN DURING THE STUDY?
Screening: Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this consent document. The screening tests and procedures listed in Table 1 below will then be performed to determine if you qualify to take part in this study.

Your participation in this study will last approximately 40 weeks (10 months) and will include approximately 16 study visits to the study center.

Tests and procedures for participants: The schedule of tests and procedures also in Table 1 below show you what you can expect at each study visit. Following this schedule is a detailed explanation of these tests and procedures.

Table 1 Schedule of Study Activities																		
	Screening	**Study Treatment Phase**							**Observation Phase**									
Week		**0**	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**20**	**24**	**28**	**32**	**36**	**40**		
Visit	**-1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**U[1]**	**ULV[2]**
GENERAL TESTS																		
Informed Consent	x																	
Medical and RA history	x																	
Comprehensive physical exam	x	x								x						x	x	x
Vital signs	x	x	x	x		x		x		x	x	x	x	x	x	x	x	x
Randomization to study treatment		x																
Brief physical exam			x	x		x		x			x	x	x	x	x			
Adverse events (side effects)		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Other medication review	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
RA questionnaires	x	x	x	x		x		x		x	x	x	x	x	x	x	x	x
Quality of life questionnaires		x								x						x	x	x
Follow-up phone calls					x		x		x									
STUDY DRUG																		
VIB4920 added to your TNF inhibitor OR Placebo added to your TNF inhibitor OR VIB4920 without TNF inhibitor		x	x	x		x		x										
CLINICAL TESTS																		
Clinical Laboratory Tests	x	x	x	x		x		x		x	x	x	x	x	x	x	x	x
Infection Laboratory Tests	x																	
Chest X-ray[3]	x																	
Tuberculosis (TB) Skin Test[3]	x																	
Blood pregnancy test for women who can get pregnant	x																	
Urine pregnancy test for women who can get pregnant		x	x	x		x		x									x	x
Research Blood Tests		x	x	x		x		x		x	x	x	x	x	x	x		x
Approximate Blood Volume for Clinical Labs *	3T	3t	1t	3t		3t		3t		4t	1t	3t	1t	3t	1t	4t	4t	4t

Table 1 Schedule of Study Activities																		
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Week		**0**	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**20**	**24**	**28**	**32**	**36**	**40**		
Visit	**-1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**U[1]**	**ULV[2]**
Approximate Blood Volume for Research Labs*		7T	3t	7T		3t		7T		7T	3t	7T	3t	7T	3t	7T		6T
AT HOME SAMPLING																		
Finger sticks and complete RAPID3 questionnaire (paper or digital application)										Weekly for Study Weeks 17-40								

[1] Unplanned visit **T=Tablespoon; about 15 mL*

[2] Unplanned last visit ** t = Teaspoon; about 5 mL*

[3] If your TB blood test result is neither positive nor negative, we will repeat the TB blood test. If the second TB blood test is neither positive nor negative, a chest X-ray or purified protein derivative (PPD) skin test is required.

Randomization: After you sign this informed consent and qualify to participate, you will be randomly assigned (like drawing straws) to one of three study treatment groups:

- Adding VIB4920 to your TNF inhibitor
- Adding Placebo to your TNF inhibitor
- Stopping your TNF inhibitor and adding VIB4920

A computer randomly picks (like drawing numbers out of a hat) which study treatment you will receive. This means that out of the 104 people in this study:

- 52 people will be assigned to have VIB4920 added to their TNF inhibitor
- 26 people will be assigned to receive placebo in addition to their TNF inhibitor
- 26 people will be assigned to stop their TNF inhibitor during the study, from Week 0 to Week 40, and receive VIB4920.

Neither you nor your study doctor are able to decide which study treatment you will receive.

Comprehensive physical exam: A more detailed and longer physical exam will be conducted at some visits to monitor your general health. During this exam, your joints will be checked, and a complete set of vital signs will be taken. You will be asked about any health events and side effects since the last visit. You will be asked to review all of the medications you are currently taking.

Brief Physical Exam: A brief physical exam will be conducted at some visits to monitor your general health. During this exam, your joints will be checked, and a complete set of vital signs will be taken. You will be asked about any health events and side effects since the last visit. You will be asked to review all of the medications you are currently taking.

Vital Signs:

- Height and weight will be taken at your first visit. Weight, temperature, blood pressure, respiratory (breathing) rate, and pulse rate will be taken at all visits.
- Temperature, blood pressure, respiratory rate, and pulse rate will be taken every 30 minutes while you are receiving your study drug and following each infusion (2 hours after the first 3 infusions and 1 hour after the last 2 infusions). We ask that you stay at least 2 hours after the first 3 doses of study treatment and 1 hour after the last 2 doses of study treatment.

RA Questionnaires: You will be asked to complete questionnaires related to how RA is affecting your joints, pain, and activities of daily living. These questionnaires can be completed using the MyOwnMed mobile application (app) which we can help you download onto your phone or MyOwnMed online which you can access on the computer. A study team member will teach you how to use the MyOwnMed versions. If you decide that you do not want to use the MyOwnMed app or online version, then the study team will provide you a paper version of the questionnaire.

Quality of Life Questionnaires: You will be asked to complete questionnaires related to how you feel physically and emotionally. These questionnaires can be completed using the MyOwnMed app, MyOwnMed online, or by paper as described in the paragraph above.

Other Medications: The study team will review all medications you are currently taking and any medication you have taken in the recent past. You can continue to take the RA medications approved by your study doctor while you are on the study. You may not take other medications that suppress your immune system such as certain doses of oral, injectable, and intravenous (IV) steroid medications. You should report any newly prescribed medications to the study doctor as soon as possible while in the study.

Study Drug: You may receive up to a total of 5 doses of the study drug, VIB4920 or placebo, during this study. The study drug is given into a vein in your arm or hand over 1 hour and 30 minutes.

Clinical Laboratory Tests (Labs): Blood samples will be collected during clinic visits throughout your study treatment and follow-up. The clinical labs include blood work to monitor your general health and your RA disease activity. If you are a woman of childbearing potential, a blood pregnancy test will be completed at the screening visit and a urine pregnancy test will be completed at the visits you are scheduled to receive the study drug or placebo. A study team member will discuss any abnormal results and what it means to you.

Infection Screening Labs: At your first visit, we will test your blood for previous exposure to HIV, tuberculosis (TB), hepatitis B virus and hepatitis C virus. We will tell you if any of these tests are abnormal and will answer any questions that you may have about these results. The study doctor may be required by law to report positive test results to the local health authority.

Chest X-ray or PPD Skin Test: If the results of your first screening blood test for tuberculosis (TB) is neither positive nor negative, we will repeat the TB blood test. If the second test is neither positive nor negative, we will ask you more questions about your history of exposure to TB. A chest X-ray or a PPD skin prick test may be done unless you have had one of those tests within the past three months. We will tell you if any of these tests are abnormal and will answer any questions that you may have about these results. The study doctor may be required by law to report a positive test result to the local health authority.

Research Labs: Research labs will be used to obtain more knowledge about your RA and how you respond to your study treatment during the study. These will include blood tests to check your body's level of the study drug and the levels of TNF inhibitor, whichever applies. These samples used for other research tests can include analysis of genetic information that may involve looking at large portions of your DNA (whole exome testing) or all your DNA at once (whole genome testing). Genetic tests study an individual's inherited characteristics, found in deoxyribonucleic acid (DNA) which is present in each of the cells of your body. DNA contains information needed to construct and operate the human body.

It is not the purpose of research studies to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. The results of research tests will not be given to you or your study doctor, and they will not be put in your medical record. They will not affect your medical care.

At Home Questionnaires and Finger Sticks: At your week 16 visit a study team member will tell you if you have had sufficient improvement in your RA to qualify for a part of the study where you will monitor the symptoms of your RA at home. If you qualify, you will be invited to obtain weekly blood samples by a finger stick to determine how your immune system changes if you have a flare of your RA. In this part of the study, if you agree, you will complete the RAPID3 questionnaire and collect finger stick blood samples at home weekly from week 16 through week 40 during the study.

RAPID3 Questionnaire:

- This is a set of questions that asks how your RA is affecting your abilities and pain level.
- We will ask you to complete your first RAPID3 questionnaire in clinic at week 16.
- At home, you can use the MyOwnMed app which we can help you download onto your phone or MyOwnMed online which you can access on the computer. If you decide that you do not want to use the MyOwnMed app or online version, then the study team will provide you a paper version of the questionnaire.
- We ask that you complete your questionnaire each week at the time you do your finger sticks for week 17 through week 40 of the study.

Finger Sticks:

- We will perform the first finger stick blood collection at the clinic during the week 16 visit.
- We will instruct you how to prick your finger at home and draw 3 to 5 drops of blood into a tiny tube.
- At home, we ask that you do your finger sticks in the morning on the same day each week for weeks 17 through week 40 of the study even if it is the same day as your study visit in the clinic.

Mailing Samples:

- We will give you overnight mailing envelopes and instructions to send the finger stick blood samples and RAPID3 questionnaire (if you use the paper form) back to the research lab each week.
- We will also provide you with a contact number in case you have questions or concerns when you get home.

Unplanned 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 or if you are not

feeling well. You will be asked to do some of the items listed on the Table 1, in column "U". Up to 1 tablespoon of blood may be taken for clinical labs at these visits.

Unplanned Last Visit: If for any reason you decide to no longer participate in this research study, we will ask you to complete one final study visit. You will also be asked to do some of the items listed on the Table 1 in column "ULV". Up to 7 tablespoons of blood may be taken for clinical and research labs at this visit.

Phone Visits: Plan to receive a telephone call during weeks 6, 10, and 14. We will ask you questions about your health and any changes since your last visit due to the study drug.

Alternate Monitoring: If at any time while you are in the study, your RA gets worse and there is a need for you to increase the dose or add certain RA medicine(s) to control your RA, you will change your study visits to the alternate monitoring schedule described in Table 2 below. If you are taking VIB4920 at this time, you will stop taking VIB4920. Your study team will review with you which RA medicines will affect the decision to change to an alternate monitoring schedule.

If your VIB4920 is stopped, or you are asked to change to the alternate monitoring schedule due to your RA getting worse, Table 2 shows how we will observe your RA activity and health until you reach week 40. These procedures are scheduled between 2 and 8 weeks apart. Alternate monitoring will include:

- A brief physical exam including a joint exam and a complete set of vital signs.
- Questions about any health events and adverse events since the last visit.
- A review of all the medication you are currently taking.
- A review of your clinical lab tests to monitor your health and RA activity.
- Questionnaires about how RA is affecting your joints and daily activities at weeks 16 and 40.

Table 2 Alternate Monitoring Schedule

Week	**2**	**4**	**8**	**12**	**16**	**24**	**32**	**40**		
Visit	**M1**	**M2**	**M3**	**M4**	**M5**	**M6**	**M7**	**M8**	**U[1]**	**ULV[2]**
Brief physical exam including joints	x	x	x	x	x	x	x	x	x	x
Vital signs	x	x	x	x	x	x	x	x	x	x
Health and Adverse events	x	x	x	x	x	x	x	x	x	x
Other medications	x	x	x	x	x	x	x	x	x	x
RA Questionnaires					x			x	x	x
Clinical Lab Tests		x	x	x	x			x	x	x
Approximate Blood Volume for Clinical Labs*		2t	2t	2t	3t			3t	4t	4t

[1]*Unplanned visit* * t = Teaspoon; about 5 mL

[2]*Unplanned last visit*

EXPECTATIONS

If you participate in this study, you will be expected to:

- Keep all scheduled appointments.
- If your study drug is stopped or you decide you no longer want to take the study drug, we ask that you consider remaining in the study for monitoring only during the rest of the 40-week study period. The information you provide is important to the science and understanding of RA and VIB4920 study treatment.
- Tell your study team if you develop new joint symptoms of pain, stiffness or swelling during the study.
- Call a study team member between visits if you have questions.
- Tell your study doctor all the medications that you are taking during the study. These include prescribed medications, over the counter medications such as pain medications or anti-inflammatories, and herbal remedies and supplements.
- Tell your study doctor if you are told there is a change in your health or if you take any new medication or new herbal remedies.
- It is very important that you do not enroll in another research study while you are participating in this trial.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

Study Drug (VIB4920) Risks: The following adverse events have been reported in VIB4920 studies in humans including healthy volunteers, individuals with RA and individuals with Sjogren's syndrome. Some of the listed adverse events were observed in persons receiving a placebo in these studies. Therefore, it is difficult to determine if the adverse events observed in these studies are related to the VIB4920 study drug.

Table 3 Adverse Events

Very common adverse events (may affect more than 1 in 10 people)	**Common adverse events** (may affect up to 1 in 10 people)	**Uncommon adverse events** (may affect up to 1 in 100 people)
• Cold or head cold • Headache • Diarrhea	• Sore throat • Cough • Stuffy or runny nose • Abdomen pain/discomfort • Ear discomfort • Cold sores • Vomiting • Increased sweating • Dizziness • Elevated liver enzymes (which can indicate liver damage) • Urinary tract infection • Low white blood cells (which can make it easier to get sick)	• Shingles
Note: One case of metastatic melanoma (a type of skin cancer that has spread to other parts of the body) was reported.		

Potential Risks

Infusion Reactions Including Allergic Reactions: As with any drug, there is a risk that you may develop a reaction to VIB4920 infusions. Infusion reactions to VIB4920 have not been reported, although the risk may exist. Reactions may develop quickly during the infusion or may occur a day or so after the infusion. These reactions may be allergic, but not all infusion reactions are true allergic reactions. Infusion reactions can include:

- Chills
- Nausea
- Cough
- Itching
- Hives
- Swelling in face
- Lowering blood pressure
- Breathing difficulty

You will be monitored closely during and after each study drug infusion and quickly treated if a reaction occurs. If you experience a mild or moderate infusion reaction you may receive medicines before additional infusions to help prevent it from happening again. These may include medications to prevent itching, such as antihistamines like diphenhydramine (Benadryl®) or cetirizine (Zyrtec®) and medications to prevent minor pain or fever, such as acetaminophen (Tylenol®). You should let the study doctor know if there is any reason you cannot or do not want to take these types of medications.

Although rare, true allergic reactions can be severe and can cause death. With severe reactions there may be:

- Swelling of the face, lips, mouth, or tongue
- Wheezing
- Difficulty in breathing or shortness of breath
- Rash or itchy raised bumps (welts or hives)
- Slow or fast heartbeat
- High or low blood pressure
- Dizziness

These reactions usually begin during or immediately after the infusion. If this happens you will be treated immediately in the clinic. Less commonly, these reactions might occur within a day or so after the infusion and in that case, you must get medical help right away.

Infections: Immune cells help the body to fight infection. Because the immune system becomes weakened following study treatment with VIB4920, you may be at increased risk of serious and non-serious infections. During the study, tell the study team if you have signs or symptoms of infection including:

- Fever
- Chills

- Cough that does not go away
- Signs of herpes (such as cold sores, shingles, or genital sores)

These signs or symptoms can happen during study treatment or after you have received your last study drug dose. If you cannot reach the study team, please contact your personal health care provider.

If you or your partner have a chronic herpes infection: VIB4920 may increase the risk of a herpes outbreak or becoming infected with herpes. It is important for people who have chronic oral or genital herpes to be aware of this risk. If you or your sex partner have been diagnosed with oral or genital herpes, we recommend the following to decrease the risk of spreading the infection:

- If an anti-herpes medicine has been prescribed, be sure to take it as instructed by your doctor.
- Keep in mind the risk of spreading herpes can increase when sores or other symptoms of herpes are present.
- Do not touch the sores or fluids to avoid spreading herpes to another part of your body. If you do touch the sores or fluids, immediately wash your hands thoroughly to help avoid spreading your infection.
- Be aware that even without sores or other symptoms, you can still infect a sex partner.
- Use of physical barriers (for example, condoms) can decrease but does not completely eliminate the risk of infecting a sex partner.

Serum Sickness: Your body may react to the VIB4920 by thinking it does not belong in your body. This may cause a potentially serious immune system disorder known as serum sickness. Serum sickness is a term used to describe a set of signs and symptoms that may develop within several days to three weeks after taking the study drug. In rare cases, it may develop as quickly as one hour after exposure in some people. The three main symptoms of serum sickness include:

- Fever
- Rash
- Painful swollen joints

Less common symptoms include:

- Headache
- Muscle pain
- Nausea
- Stomach cramps
- Diarrhea
- Swollen lymph nodes
- Blurred vision

There may be other risks from VIB4920 study treatment that are unknown at this time.

Your study doctor may decide to stop your study drug if you develop a complication listed above. We will ask you to stay in the study so we can monitor your overall health.

RISKS OF STUDY PROCEDURES

Blood Draw Risks: Possible side effects from having blood drawn include dizziness, fainting, 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).

Intravenous (IV) Catheter Risks: The risks involved with using IV catheters are rare and often mild. They include minor discomfort, bleeding, and bruising at the needle site. These symptoms often get better without medical help. You may also have some restriction of movement during the infusion time. Infection (indicated by redness, warmth, pain, swelling, or drainage at the needle site) can occur.

Vaccine Risks: VIB4920 interferes with your immune system's response to an infectious agent such as a virus or bacteria and may not provide the same level of complete protection after receiving a vaccine. Please speak to your primary care provider or rheumatologist to make sure you are up to date on all recommended vaccinations to increase your protection against infections as much as possible.

This study drug may also increase your risk of infection after receiving a live vaccine (for example: mumps, measles, and rubella). You cannot receive a live vaccine within 30 days before entering this study. If you receive a live vaccine during the study, your study drug will be stopped.

We strongly recommend that you follow CDC guidelines and are up to date on your non-live vaccines at least 14 days before you enter the study. This includes the flu and COVID-19 vaccines. Please tell a study team member if you plan to receive a flu vaccine during the study so that your medications can be adjusted, if necessary. You should not receive any other vaccines from the start of receiving study drug (week 0) to 8 weeks after your last dose of the study drug.

If you plan to receive a vaccine during the study, it is important to discuss it with the study team so your medicines, such as methotrexate can be temporarily adjusted for optimal response to the vaccine.

RA and Quality of Life Questionnaires: You may feel uncomfortable answering some of the questions. If you do not wish to answer a question, you may skip it and go to the next question.

Risk to Confidentiality and Privacy: If you qualify for the part of the study that asks you to complete weekly questionnaires and provide blood samples, you may use the MyOwnMed app,

MyOwnMed online or use a paper questionnaire. By choosing to use the MyOwnMed app or online version, you agree to be bound by the Terms of Use (TOU) and Privacy Policy. These documents may be accessed using the App. If you are using a paper version of the questionnaires, the TOU and Privacy Policy will be provided to you in paper form.

While using the MyOwnMed app or online, data about you including your RAPID3 information, any personally identifiable information that you provide, and information about your mobile device will be collected and transmitted to the researchers. A complete description of this data collection and sharing is found in the Privacy Policy. Safeguards are in place to protect your personal information; however, transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your information and safeguards are in place to protect your personal information.

While the MyOwnMed Terms of Use may include statements limiting your rights if you are harmed in this study, these statements do not apply to your use of the app in this research study. In addition, you do not release the study doctor, sponsor, institution, or agents from responsibility for mistakes.

BIRTH CONTROL RESTRICTIONS

You cannot participate in this study if:

- You are pregnant or planning a pregnancy during the 40 weeks of the study.
- You are breastfeeding.
- You are of childbearing potential and you or your partner are unable or unwilling to avoid pregnancy.

If you are a male or female who engages in sexual activity that could lead to pregnancy you need to agree to use one of the acceptable methods of birth control listed below from at least 2 weeks prior to your first dose of study drug until 24 weeks after the last dose of study drug, even if you leave the study early.

Acceptable forms of birth control include:

- Oral birth control pills (combined hormone or progestin alone)
- Injectable or implantable progestogens
- Intrauterine devices (IUD) or estrogen vaginal rings
- Double barrier methods (for example, condom and occlusive cap with spermicidal agent)
- Tubal ligation
- Male sterilization (this must be a female participant's only male partner)

Periodic abstinence and withdrawal are not acceptable methods of contraception.

Even if you are using birth control or are sexually inactive (complete abstinence), all female participants will be given a pregnancy test before and during the study. You and your study doctor will discuss acceptable methods of birth control.

If you or your partner become pregnant while in this study, or if you think that you have become pregnant, you must contact your study doctor. We will continue to follow you until the baby is born or the pregnancy stops. Your study team will ask you about the length of the pregnancy, whether it is ongoing, whether a baby was born, and the health of the baby.

ALTERNATIVES TO PARTICIPATION
Before you decide to take part in this study, your study doctor will talk with you about other treatment options available to you. There may be other research studies that you can choose to join.

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.

BENEFITS
This study is not designed to provide direct benefit to you. What we learn from this research may benefit society and help others with RA in the future.

COMPENSATION FOR PARTICIPATION
You will be given $50 for each visit to cover travel, parking and other expenses associated with study participation. Additionally, for each of the study drug infusion visits you will receive $100 per visit, and for each of the other clinic visits you will receive $75.

If you participate with the weekly home finger sticks and RAPID3 questionnaires, you will be paid an additional $25 each time you provide both a finger stick blood sample and submit a completed questionnaire**.**

The total amount you may receive for taking part in the study and completing all visits ranges from $1,625 to $2,075.

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

Your samples and study data will be identified by a code. We will store the code linking your identity to study data on a password protected, secured computer. The only people that will have access to this are your study doctor and approved study team members. The purpose is to make study data available to other researchers, without disclosing your personal information, such as name, phone number or address. You will not be identified in any publication or in the sharing of your data from this study.

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 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.

As an 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 study.

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 participants.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the study that is needed for auditing or study evaluation by the agency which is funding this study 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.

Organizations that may access your medical records for research, quality assurance and data analysis include:

- National Institute of Allergy and Infectious Diseases (NIAID), its representatives, agents, employees, contractors, and other persons involved with conducting, and monitoring the study and analyzing the study results
- U.S. Food and Drug Administration (FDA)
- Federal and state agencies and other regulatory authorities
- Amgen, the company that makes VIB4920, the study drug being studied
- Advarra Institutional Review Board (IRB)

Additionally, MyOwnMed, Inc., the company that makes the app used for the RAPID3 questionnaire will have access to the RAPID3 responses.

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.

COMPENSATION FOR INJURY

If you are injured or get sick while in this study, it is important to tell your study doctor. If you should be injured as a result of your participation in this study, emergency medical care is available to you, but the costs of this care will be charged to you or your insurance company. The hospitals and/or treating physicians reserve the right to bill you and/or your insurance provider(s) for services you receive for the injury. No payment or additional compensation is available to you as a result of such injuries. There is no provision for free medical care or monetary compensation from the study sponsor, the NIAID/NIH. You do not lose any legal rights by signing this form.

COSTS

VIB4920 is being provided by Amgen, without cost. The costs of all tests and procedures described above that are required by the study will be paid by NIAID through the Immune Tolerance Network (ITN). You will be responsible for any expenses related to your routine clinical care, including the costs of all medications you were taking when you started the study (for example, TNF inhibitor, methotrexate, leflunomide) and will continue during the study. 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 treatment when individuals are participating in a research study. 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.

FUTURE RESEARCH STUDIES

Stored Samples and Information: If you agree, we will store your blood samples and information in the Immune Tolerance Network (ITN) repository located in the United States for an unknown length of time. 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. Stored blood samples and information may include future genetic research including whole genome or whole exome sequencing.

Samples and related information stored at the ITN repositories will be stored with a code after your personal information is removed so that your name and personal information will not be identifiable to ITN**.** The coded samples will be stored without your name or other information that might identify you. If samples are shared with an outside investigator, they will be sent with the assigned code so that the samples cannot be traced to you by an outside investigator. We will not ask you for additional permission before sharing this information.

There may be risks in allowing the storage, sharing or analysis of samples and information. For example, 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. If information resulting from analysis of your samples is shared publicly, it will not contain personal identifiers (for instance, your name, birthday etc.).

You can change your mind at any time during the study and ask to have your stored samples destroyed. This request should be made 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.

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.

Although your stored study samples will not be sold, the information obtained from the research performed on your samples may in the future lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

Please consider the storage of leftover blood samples for future use as described above and answer the question below. No matter what you decide, it will not affect your care or participation in this study. The choice is up to you.

Please indicate your response below:

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

☐ **Yes** ☐ **No**

_____
Initials of Research Subject

Please indicate your response below:

If you qualify for additional sample testing, do you agree to do all of the following:

- **Perform weekly finger sticks and return in the sample envelope provided?**
- **Complete weekly questionnaires using one of the following: MyOwnMed app, MyOwnMed online or paper questionnaire form?**
- **For those using a paper questionnaire form, do you agree to return the form in the questionnaire envelope provided?**

☐ **Yes** ☐ **No**

_____
Initials of Research Subject

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 such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures.

Please contact the study doctor 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 participants. If you have any questions about your rights as a research participant, contact**:**

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00064469.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your continued participation is voluntary. You may withdraw from the study at any time for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that any information collected up to the point of your withdrawal cannot be removed from the study files.

If you decide to leave the study early, you will be asked to complete one final study visit.

Other Reasons for Stopping: 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 determines that it is in your best interest not to take part.
- You are unable to complete required study treatments and examinations.
- You become pregnant or plan to get pregnant during this study.
- The study is stopped by the study site, the Sponsor(s), or by the FDA or other health authorities.

If you are removed from the study your study doctor will notify you about treatment or procedures for your continued care.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study team 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 team 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 Immune Tolerance Network.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other U.S. 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 study 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 study, 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.

In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign this authorization document.

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 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 team 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 this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date