CONSENT TO PARTICIPATE IN RESEARCH AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Mindera Corporation / "A 16-week randomized evaluation of the impact of Mind.Px Application on response to biologic treatment in patients suffering from plaque psoriasis Through Clinical utility and Health outcomes. (MATCH STUDY)"**
Protocol Number:	**MND-21-MKPs-02**
Principal Investigator: (Study Doctor)	**C. Kent Kwoh, MD**
Telephone:	**520-626-8379** **520-694-6000 (24-Hour)**
Address:	**University of Arizona Arthritis Center** **1501 North Campbell Avenue** **Room 8303** **Tucson, AZ 85724**

Purpose of the Information and Consent Form

The purpose of this form is to give you information about this research study and, if signed and dated, will give you permission to take part in the study. Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. This form will describe all aspects of the research study, including the purpose, procedures, benefits, risks, discomforts and precautions. Your participation is completely voluntary and you should only take part in the study only if you want to do so. If you decide not to be in the study or you change your mind during the study, you can withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. The study doctor, study staff, Advarra Institutional Review Board (IRB) or the sponsor can remove you from the study at any time, even if you want to stay in the study.

This could happen if:

- The study doctor or study staff believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- The sponsor or Advarra stop the study for any reason.

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. The study doctor or study staff may ask you to participate in some procedures or tests

to help you leave the study safely and/or to collect more information for the study. If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected.

If you are a student, your participation will not place you in good favor with the study doctor or other faculty (for example, receiving better grades, recommendations, employment). Also, not participating in this study will not adversely affect your relationship with the study doctor or other faculty.

If you have any questions about the study or do not understand something in this form, you should ask the study doctor, study staff, or anyone that you choose in order to help you better understand the study and your options. You should not sign and date this form if you do not understand something, do not have all your questions answered or if you have questions that have not been answered to your satisfaction. You may take home an unsigned copy of this form to get a second opinion from family and friends before making any final decisions.

You must be honest with the study doctor about your health history or you may harm yourself by participating in this study.

In this document, you may see the term "treatment"; this is a term used in research studies as mentioned above and does not mean that you will be receiving medical treatment for any condition. These terms apply to the study device and parts of the study where the investigational device will be used.

The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.

WHAT IS THIS STUDY ABOUT?

Researchers want to find out more about an investigational device called Mind.Px. The main purpose of this study is to see if Mind.Px can be used to provide information that could guide the selection of therapies to treat psoriasis. The Mind.Px study device includes the most commonly prescribed biologic therapies for the treatment of psoriasis (anti-TNF-α, anti-IL-17 and anti-IL-23 biologic classes). Mind.Px is an unapproved test, and its role in trying to guide treatment decisions is unproven.

It is not clear whether Mind.Px actually impacts subject response to biologic treatment. For this reason, you will be assigned to a group using a method called randomization. Randomization means that the group you are in is assigned by chance, like the flip of a coin. Your chance of being in the group in which the treating physicians are aware of Mind.Px results or being in the group that receives treatment as usual is equal. The Mind.Px report will only be issued to your study doctor if you are in the group utilizing Mind.Px. The treatment as usual group's study doctors will not have the results of this report until the end of the study and will not use this to make treatment decisions. You will not know which group you are in until the end of your participation in the study.

In order to make use of the Mind.Px study device, an RNA sample from lesional skin must be collected from subjects. This is done via the Mindera Kit (MK). This investigational device is a topical patch (will be placed directly on your skin) that is being tested and is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA).The patch is a method of gathering RNA material from your skin before you start anti-TNF-alpha, anti-IL-17, or anti-IL-23 therapy. Your cells have DNA which contains your genes and directs cells to make RNA. The role of RNA is to translate the information from

DNA and transmit it to cells that will do the work. The patch collects the RNA material. It is not your DNA or genes but it may point to some genes in psoriasis that could help develop new medications.

This study will enroll approximately 200 male and female subjects 18 years and older with clinical diagnosis of psoriasis who intend to be treated with anti-TNF-alpha, anti-IL-17, or anti-IL-23 biologic either as part of their routine psoriasis care. This study does not include treatment for your psoriasis. The choice of psoriasis treatment will be up to you and your physician alone. Your study doctor may choose to act on the results of the Mind.Px sample or not.

Once enrolled, the planned length of participation is approximately 4 months.

The study will be done at approximately four or more clinical sites throughout the United States.

HOW DOES MK WORK?

MK is a patch that will be directly applied on the skin affected by psoriasis. This study device contains no active medication.

WHAT ARE MY RESPONSIBILITIES IF I PARTICIPATE IN THIS STUDY?

- Be willing and able to follow the study directions and procedures
- Tell the study staff about any side effects or problems
- Tell the study doctor or the study staff if you change your mind about staying in the study

WHAT ARE THE RESTRICTIONS/REQUIREMENTS FOR BEING IN THIS STUDY?

The study doctor and/or study staff will explain all requirements and restrictions for being in this study.

- The study doctor will review all past, recent, and current medications you have taken to ensure you meet all study entry requirements
- You must be diagnosed with psoriasis, and the affected area must be greater than two centimeters in diameter or about the size of a penny

IS THERE ANYTHING ELSE I CAN DO FOR MY SYMPTOMS?

This study is not designed to treat your current symptoms. The only other option is to not participate.

WHO IS PAYING FOR THIS STUDY?

A biotechnology company called Mindera Corporation, the Sponsor of the study, is paying for this study and will provide the study device to you at no cost. As part of the study there are no other medications which will be given or prescribed to you by the study doctor. You will be billed for your regular care while participating in this study as usual. Usual care includes (but may not be limited to) your usual medications, exams, imaging, lab work, biopsies, etc.

We do not expect any additional cost to you to be in this research study.

HOW LONG WILL I BE IN THE STUDY?

If you agree to participate in this study, and the study doctor verifies that you meet all the criteria for being in the study, your participation could last up to 4 months.

The study doctor might stop your study product application if your condition is getting worse or if you have bad side effects. Your study participation will also stop if you decide to withdraw from the study or the study ends.

You may visit the study center to have the procedures and tests described in this form or some procedures and test may be done remotely. Ask the study doctor or study staff for further information about your study visit schedule.

WHAT WILL HAPPEN DURING THIS STUDY?

You will need to sign and date this Informed Consent Form (ICF) prior to undergoing any screening procedures.

Pre-study evaluations (screening) may be performed on the same day that you receive the study device if you are qualified to enter the study.

Screening Visit 1:

After you have signed and dated this consent form, the study doctor or study staff will perform assessments to determine if you are eligible to participate in this study.

If the initial evaluation (called Screening) confirms that the study is suitable for you, you will be enrolled in the study. The study doctor will obtain your medical history and may do a short physical exam to determine where MK can be put on. The patch will stay on your skin for 5 minutes before it is removed and sent to a lab for analysis.

After the very first visit, you may be asked to return to the clinic five more times. All enrolled subjects are expected to complete a study visit at Weeks 4, 8, 12, and 16. The MK patch will be applied on your skin for 5 minutes and then removed during the screening visit..

During this study, you will have various assessments done which will look at the potential of MK. The below tests will be completed at each visit.

- **Collecting your Medical History and Medications:**
  - You will be asked questions about your health and skin disease history at your first visit, including any procedures and medications within the past three months.
  - At each visit you will also be asked about medications you are using now and any changes to those medications as well as any changes in your skin and overall health.
- **Demographic Questions:**
  - You will be asked questions about your race/ethnicity and date of birth.

- **Physical Examination:**
  - Your study doctor will do a brief exam to assess your health status. This will be done either at the screening visit or the baseline visit. You will have your height and weight measured.
- **Psoriasis Area and Severity Index (PASI):**
  - Your study doctor will perform a test called Psoriasis Area and Severity Index (PASI) to measure the size of your skin affected with psoriasis and the severity of your condition.
- **Physician Global Assessment (PGA):**
  - Your study doctor will perform a test called Physician Global Assessment (PGA) to measure the severity of your skin affected with psoriasis and the severity of your condition.
- **Body Surface Area (BSA):**
  - Your study doctor will perform a test called Body Surface Area (BSA) to measure the size of your skin affected with psoriasis and the severity of your condition.
- **MK Application:**
  - If you qualify for this study, a selected area of your skin will be tested with the study device MK. The patch will be applied on your skin and the study staff will hold this patch for 5 minutes before removing it. The study area will be assessed before and after the application of the study product to check for any side effects. Your study staff will perform the application at the screening visit only..
- **Dermatology Life Quality Index (DLQI), 36 Item Short Form Survey (SF-36)**
  - You will be asked questions about your health and skin disease at visits 2-6.

Early Termination Visit: If you are withdrawn from the study, or choose to withdraw from the study, you will not be required to return for another checkup. You will need to notify your study doctor if you decide to withdraw your consent to participate in this study.
It is very important that you talk with the study doctor or study staff before starting or stopping any other medications during this study.

WILL BEING IN THIS STUDY HELP ME?

You may or may not benefit from taking part in this study.

Your skin condition will be carefully monitored during this study. Your participation in this study will provide information that may help contribute to the development of better treatments for patients with psoriasis.

WHAT ARE THE SIDE EFFECTS/RISKS TO ME IF I AM IN THIS STUDY?

Risk of the Study Device Used in This Study (MK):

If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you.

You may experience some reactions to the study device. All of the side effects may not be known and there may be risks that are unknown and unforeseeable at this time. Information about possible side effects from the use of MK is based upon the experiences of subjects who have used it in the past and

tolerated it well. The most common risk is a sensation of discomfort or pressure with application of the patch.

Side effects have not been reported thus far. It is not possible to predict whether you will experience any side effects.

If you have any questions about the potential side effects, please ask the investigator or study staff for explanation.

Allergic Reaction: It is possible that you could experience an allergic reaction to the study device. Symptoms of any allergic reaction can include:

- Rash,
- Hives, (bumpy red rash)
- Itching.
- There are theoretical risks of delivery of small amounts of DNA into your skin, inflammation, and infection. These have not been reported to date.

Once the study device has been applied to your skin, you will be monitored carefully for signs of an allergic reaction.

It is very important that you tell the study doctor and study staff about any side effects that you experience. If you are not honest about your side effects, you may harm yourself by staying in the study.

What Happens To My Samples Collected For Research?

After removal, each MK that was put on your skin will be placed in a solution, then sealed and sent to a lab for analysis.

WILL I RECEIVE ANY NEW INFORMATION DURING THE STUDY?

If the study doctor or study staff learns any significant information that might change your mind about continuing in the study, the study doctor or study staff will tell you about it. You can then decide if you still want to be in the study. You may be asked to read, sign, and date a new consent form.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If you are injured as a result of having the study device applied on your skin for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury if the injury is directly caused by administration of the investigational patch or a procedure required by the protocol that is not part of your usual and regular care. The sponsor will not pay for any medical expenses if the injury is caused by the study team's failure to follow the sponsor's protocol or any sponsor instructions, any underlying illness, or if the costs have already been paid by your medical insurance. No other compensation is offered (for lost wages, mental distress, etc.) beyond that which is listed in this informed consent document. You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing and dating this consent document.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

WILL I LOSE MY LEGAL RIGHTS BY SIGNING AND DATING THIS FORM?

You do not lose any of your legal rights by signing and dating this consent form.

WILL I RECEIVE PAYMENT?

You will be paid $105 per protocol required completed visit to help offset any additional travel expenses you might have due to your participation. You will only be paid for those visits you complete. You will be paid following each completed visit.

No other payment or compensation will be offered for your participation in this study. You also will not receive any payment or compensation as a result of any development or commercial sale of the study device. If you have any questions regarding your payment for being in the study, please contact the study doctor at the telephone number listed on page one of this consent document.

Compensation for participation in a research study is considered taxable income for you. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes.

For any compensation or reimbursement you receive, we are required to obtain identifiable information such as your name, address, and Social Security number for financial compliance purposes.

WILL MY STUDY-RELATED INFORMATION BE SHARED, DISCLOSED, AND KEPT CONFIDENTIAL?

If applicable, you may need to answer the study doctor or study staff's questions. This could lead you to feel uncomfortable or upset. Please tell the study doctor or study staff if you feel uncomfortable or upset while answering questions. You have the right to refuse to answer any questions.

It is anticipated that there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose your PHI for this study. Your

information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups include:

- Office For Human Research Protections or other federal, state, or international regulatory agencies
- Food and Drug Administration
- *Banner University Medical Group and Banner Health*
- Advarra IRB
- The University Of Arizona (UA) And The UA Institutional Review Board
- The sponsor supporting the study, their agents or study monitors
- Your primary care physician or a specialist taking care of your health.

If you agree to take part in this study a copy of this signed informed consent form will be saved into your electronic medical record (EMR) at Banner Health. As a result, healthcare providers and staff who are not working on this study, but who may provide you medical treatment in the future, will know that you are taking part or took part in this study.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?
Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

- Information from your medical records
- Information collected about you during the research about your study visits, tests, and procedures (including the results of drug tests)

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number. If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.
Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and study sponsor's monitor may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

When will my authorization expire?
There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

Do I have to sign this authorization form?
You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

What do I need to know if I decide to cancel my authorization?
After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. The Principal Investigators address and telephone numbers is listed on the first page of this form.

Will access be limited to your research study record during this study?
You may not have access to the research information developed as part of this study until it is completed.

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 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 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
  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: Pro00056531.

A description of this clinical trial will be available on http://www.ClincialTrials.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 anytime.

If you have questions, concerns, or complaints about the use or sharing of your health information or would like a copy of the Banner Notice of Privacy Practices, you may contact the Banner Research HIPAA Liaison at 602-839-4583 or BHResearchCompliance@bannerhealth.com.

To cancel your authorization for access to PHI you must notify the study doctor listed on page one of this document.

CONSENT

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study. They have answered all my questions. I voluntarily agree to be in this study.

By signing and dating this form, I do not give up any of my legal rights. I will get a signed and dated copy of this consent form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

I attest that the individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this study.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date

I attest that I or my representative discussed this study with the individual providing consent.

_____
Signature of Principal Investigator or Sub-Investigator