RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	An Exploratory Trial to Evaluate the Clinical Effectiveness of a Topical Application of BMX-010 in Subjects with Rosacea **Part A**
PROTOCOL NO.:	BMX-DERM-202 WIRB® Protocol #
SPONSOR:	BioMimetix JV, LLC
INVESTIGATOR:	Name Address City, State, Zip Code Country
STUDY-RELATED PHONE NUMBER(S):	Name Phone Number(s) (24-hour number required)

A person who takes part in a research study is called a research or study subject.

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all of your questions are answered.

PURPOSE OF THE STUDY

You are being asked to take part in this research study because you are at least 18 years old and have diagnosis of Rosacea. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed in this document.

Please tell the study doctor or study staff if you are taking part in another research study.

[Principal Investigator name] will conduct the study and it is funded by BioMimetix JV, LLC, the sponsor of this study. BioMimetix JV, LLC, will pay [institution name] to perform this research, and these funds may reimburse part of [Principal Investigator name] and his/her research team's salaries.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, [Principal Investigator name] or one of the other doctors at [institution name] will be your doctor for the study. If you choose, your study doctor or a

member of the research team will notify your regular health care provider about your participation in this study.

Do you give permission for the study doctor to contact your regular health care provider about your participation in this study?

_____Yes

_____No

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to first evaluate the optimum formulation, concentration, and dosing frequency of the study drug in the first part (Part A). The word "investigational" means the study drug is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA).

The investigational study drug (BMX-010) is available in both gel and cream topical formulations. We would like to test what works best in patients with Rosacea. BMX-010 is also available in 0.03% and 0.1% concentrations, so we would like to test what works best in patients with Rosacea. Finally, we would like to see if BMX-010 works best to when used once or twice a day. All participants in Part A will receive the study drug.

BMX-010 is thought to treat a wide variety of inflammatory disorders.

This is a Phase 2 study. The safety of BMX-010 has previously been confirmed in Phase 1 studies. We will continue to monitor your safety while on the study. Please carefully read the sections on risk and benefits below.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Up to 60 people will participate in Part A of this study at up to twenty institutions in the United States.

WHAT IS INVOLVED IN THIS STUDY?

Screening and Baseline Evaluation(s)

If you agree to be in this study, you will be asked to sign and date this consent form. This may be done up to 14 days prior to receiving the study drug. Before receiving the study drug, you will be asked to do the following tests and procedures to make sure that you are eligible. If schedules allow, it is acceptable to combine your screening evaluation with the baseline (Day 1) evaluation, and start the study drug on the same day. The following will occur to determine if you are eligible. This is called screening:

- Vital signs, including blood pressure
- Height and Weight
- Past Medical History and physical exam
- Review of current medications
- Review of medical and demographic information
- Blood draw (by needle stick) for hematology (blood counts) and blood chemistry tests
- Urine pregnancy test, if you are female of childbearing potential
- Evaluation of severity and extent of Rosacea, this includes counting the lesions on your face and measuring the redness of your Rosacea
- You will be asked a series of questions about your disease and the study drug at the baseline visit.

There are some requirements regarding your skin care regimen that you must understand in order to participate. Please review the following list before agreeing to participate.

1. You must be willing to refrain from using any topical or systemic treatments for inflammatory skin disease, other than the investigational product.
2. If you need to use a cleanser, moisturizer or sunscreen during the study, you must be willing to use only allowed cleansers, moisturizers, sunscreens, or moisturizer/sunscreen combination products. If you wear makeup you must agree to use non-comedogenic makeup (*non-comedogenic makeup denotes a skin-care product or cosmetic that is specially formulated so as not to cause blocked pores)*.
3. If you have a beard or excessive facial hair at Screening which would interfere with the study treatments or study assessments and refuse to remove for duration of study, you cannot participate.
4. You cannot use medicated make-up (including anti-aging make-up) throughout the study;
5. You cannot use any of the following treatments on your face while in the study: 1) topical steroids, 2) topical anti-inflammatory agents, 3) topical antimycotics, 4) any topical rosacea treatments or 4) topical antibiotics.
6. You cannot use medicated cleansers on your face throughout the study.
7. Within 2 days prior to Baseline and throughout the study you cannot use topical astringents or abrasives, medical topical preparations (prescription and OTC products).

If you have questions about your products and if they fall into any of these categories, please discuss with the study team.

After completion of the screening process, the doctor will determine whether you are eligible to participate in the treatment part of the study. If you are eligible and you choose to participate, you will be enrolled in the study. If you do not meet the eligibility requirements, you cannot take part in this study, in which case your doctor will inform you of other options that are available to you.

Study Procedures

After screening, if you are eligible, there will be 6-7 weekly visits. The treatment period of the study (when you will apply the study drug) will consist of approximately 1-28 days, with a final follow-up on Day 43. After the final follow-up visit, the clinical center may call you up to three times at approximately 1, 2, and/or 3 month following the Day 43 visit to ask a few questions about your Rosacea status and medications. This call should only last 5-10 minutes.

All subjects who enroll in Part A will receive the study drug.

You will be given the study drug to take home and apply to Rosacea on your face from Days 1 to 28. The doctor will let you know if you should apply it once or twice a day. You will return to the clinical center weekly. You will bring the study drug tubes (even empty ones) back with you to the clinic at each weekly visit for review by study staff. If the study doctor determines that your Rosacea has cleared from using the study drug before the treatment period is over, they will assess and let you know if you should continue dosing with the study drug or stop. Your study doctor may instruct you to keep returning for weekly visits or they may ask you to wait until the final, Day 43 visit. The study team will discuss this in more detail with you.

Physical examinations, vital signs (temperature, respiratory rate, blood pressure and pulse), and weight will be performed at each weekly visit throughout the study. The doctor will also review your rosacea and count the inflammatory lesions on your face, as well as make an assessment of your disease severity and the redness of your Rosacea. Each week, you will be asked a series of questions about your disease and the study drug. The weekly visits are on Days 1, 8, 15, 22, 29, and 43.

Pregnancy Test: For women of childbearing potential, a urine test to rule out pregnancy will be done within 48 hours prior to administering the study drug if applicable, and also on the Day 43 visit.

Blood Tests: Blood will be drawn for testing from all subjects twice times during the study period. Approximately 2-3 teaspoons of blood will be drawn from your arm by a needle stick for evaluation before starting study drug. This will be repeated on Day 43. You should fast for 8 hours prior to having your blood drawn. Blood tests will include complete blood count (CBC with differential) and complete metabolic panel (CMP) tests. In total, approximately 4-6 teaspoons of blood will be drawn over the 43-day study period.

Lesion Photographs: You will have the option to decide if you want lesion photographs performed. If you agree to do this, photographs will be offered at Baseline and each weekly visit (Days 8, 15, 22, 29, and 43). The photographs will show your face.

Do you consent photographs?

_____Yes

_____No

Additional tests may be done at the discretion of your physician as part of your regular care throughout the study. These exams and tests will be done to monitor the effects of study drugs.

You should contact your study doctor at any time to let him or her know of any bad side effects that you might be having.

HOW LONG WILL I BE IN THIS STUDY?
You will be asked to come to the clinical center up to 6-7 times over the course of 43 days and each study visit will take approximately 1 hour. There may also be follow-up phone calls up to 3 months after the Day 43 visit which will take about 5-10 minutes each.

You will receive the study drug, on Day 1 (Baseline). It will be applied on this day by the study staff and they will provide instructions on how much to apply. You will apply the drug at least once a day, but possibly twice if indicated by the study doctor for a minimum of 7 days and a maximum of 28 days and you will be followed for about 43 days in this study. You should bring the study drug (including empty tubes) with you every time you go to the study doctor's office. It will be collected on Day 29 or Day 43. When you have the study drug at home, you should store it in the refrigerator.

The study doctor may take you off the study if new scientific developments occur that indicate the treatment is not in your best interest, or he/she feels that this treatment is no longer in your best interest.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
Evaluation of possible side effects in human subjects is an important component of this study. You will be evaluated for local skin irritation in response to the study drug and evaluated for any additional symptoms. If local skin irritation occurs, you should stop the drug and call the study doctor to report the effect.

As a result of your participation in this study, you are at risk for the following side effects:

BMX-010 (study drug) may cause some, all or none of the side effects listed below. Side effects are dose-dependent and the relatively low doses of this drug planned in this study have not been associated with side effects in animals other than those related to the color of the injected drug.

The most common side effects (expected to occur in more than 30% of subjects) are:

- Yellow to brown discoloration of the skin at the administration site which may take several days to resolve.
- Discoloration of clothing or materials coming into contact with the treated skin.

Less common side effects (expected to occur in less than 10% of subjects) are:

- Skin irritation at the administration site.

Additional possible side effects are:

- Light-activated skin rash in response to sun exposure (this has not been reported by any patients enrolled in Phase 1 of the study drug).
- It is also possible that previously unobserved and unexpected side effects could occur.

Blood Draws: The collecting of blood samples to monitor your health throughout this study may cause mild discomfort or pain from the needle puncture and possible bruising or mild bleeding. The risk of infection is slight and will be further reduced by keeping the puncture site clean and dry.

Confidentiality: There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. You may stop your participation in this study at any time.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

For those of Reproductive Potential

Female

Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a urine pregnancy test will be done and it must be negative before you can continue in this study. It will also be done at the end of the study. If sexually active, you must agree to use two appropriate contraceptive measures for the duration of the study and for 1 month afterwards. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B$^{(TM)}$, sold for emergency use after unprotected sex, are not acceptable methods for routine use. If you do become pregnant during this study or if you have unprotected sex, you must inform your study physician immediately.

There may be side effects that are not known at this time.

Women who are pregnant or nursing a child may not take part in this study. Before entering the study, you and your study doctor must agree on the methods of birth control you will use during the entire study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study and followed until after the end of the pregnancy.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, or for your care, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of [institution name] with the exception that your date of birth and dates of service may be recorded. For all other records disclosed outside of [institution], you will be assigned a unique code number. The key to this code number will be kept by your study doctor. As part of the study, [Principal Investigator name] and [his OR her] study team will report the results of your study-related tests to the sponsor, BioMimetix JV, LLC. "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

Study-related tests would include laboratory tests such as your blood counts. Research records, records about phone calls made as part of this research, and records about your study visits may also be shared with the sponsor. In addition, your records may be also reviewed in order to meet federal or state regulations including review by the United States Food and Drug Administration (FDA). If you consent to the photographs, they may be shared with the sponsor.

A Clinical Safety Committee (CSC) may be utilized to review this study. The purpose of this committee is to review safety data and make recommendations.

Reviewers may include representatives of BioMimetix JV, LLC, Western Institutional Review Board and other individuals and organizations contracted by the sponsor. If this group needs to review your research record, they may also need to review your entire medical record. This information may be needed to do the research, to study the results, and to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

You do not have to give permission to use and give out your health information, but then you will not be able to be in this research study.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study. (Or, "Permission to use and disclose your health information will expire on _____ unless you withdraw your permission before that date as explained above") {For sites in WA, CA, IND. IL, WIS, DEL.}

You may have the opportunity to review or copy your information, but only after the research is over.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

There is a risk that your information will be given to others without your permission.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
The potential benefits may include protection against skin inflammation such as that experienced in Rosacea. The benefits may be long lasting. Because this this study is experimental, it cannot be guaranteed that you will receive any benefit as a result of participating in this research study. We hope that in the future the information learned from this study will benefit other people with your condition.

During this research project, new information regarding the risks and benefits of the study may become known to the investigators. If this occurs, they will tell you about this new information. New information may show that you should no longer participate in the research. If this occurs, the persons supervising the research will stop your participation in it. New information may also require you to sign a new consent form. In either case, you will be offered all available care that suits your needs and medical conditions.

WHAT OTHER OPTIONS ARE THERE?
Instead of being in this study, you have these options:

- You could choose to receive already approved marketed drugs.
- You could choose to receive no treatment at this time.
- You could participate in another research study if one is available.

Any decision you choose will in no way affect the regular care that you receive. Please talk to your doctor about these and other options.

WHAT ARE THE COSTS?
There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. In order to make sure that tests and studies done solely for research purposes are charged correctly, we will carefully monitor your charges as long as you are participating in this study. These tests and studies are not a part of routine care, and people who are not part of the study do not usually have them performed. Please ask [Principal Investigator] if you would like to know more about which tests and studies are being done solely for research purposes.

BMX-010 is provided free of charge by BioMimetix, JV LLC while you are on study.

The Blood draw (by needle stick) for CBC and CMP are research-related costs and will not be charged to you or your insurance.

If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

WHAT ABOUT COMPENSATION?
You will receive $X for your travel and participation time for each completed visit for taking part in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at [Institution name] in the event that you are injured as a result of your participation in this research study. However, there is no commitment by [Institution name], BioMimetix, JV LLC, or your physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact [Principal Investigator] at [phone number] during regular business hours and at [24 hour phone number] after hours and on weekends and holidays.

By signing this consent form, you are not giving up your right to seek legal recourse for your injury.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at [institution name]. If you do decide to withdraw from the study, we ask that you contact [Principal investigator] in writing and let [him OR her] know that you are withdrawing from the study. [His OR Her] mailing address is [mailing address].

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. A reason why this might occur includes new identification of an unexpected problem with the study drug. If this occurs, you will be notified and your study doctor will discuss other options with you.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions, complaints or suggestions about the research, contact [Principal Investigator] at [phone number] during regular business hours and at [24-hour phone number] after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns, questions, complaints or suggestions related to the research, or to obtain information or offer input about the research, contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

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

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the release of my medical and research records for the purpose of this study.

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

_____
Subject Name (printed)

CONSENT SIGNATURES:

_____ _____
Signature of Subject Date

_____
Name of Person Conducting Consent Discussion (printed)

_____ _____
Signature of Person Conducting Consent Discussion Date