Permission to Take Part in a Human Research Study

Title of Research Study: *Development & Preliminary Clinical Validation of Blue Light Phototherapy Systems for T-Cell Mediated Skin Diseases*

Investigator: ***Dr. Shuai (Steve) Xu***

Supported By: This research is supported by T-Cellerate LLC and the Principal Investigator Dr. Steve Xu.

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because have a history of Grover's disease or psoriasis vulgaris, and are not currently taking any systemic medications to treat either disease.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
The purpose of this research is to determine the efficacy of blue light therapy on treating patient's with either Grover's disease or psoriasis vulgaris.

Grover's disease is a rare skin condition that causes sudden red, raised, blistery, and sometimes very itchy spots around the middle of the body. Another name for this condition is transient acantholytic dermatosis (TAD).

Psoriasis is a chronic skin condition caused by an overactive immune system. Symptoms include flaking, inflammation, and thick, white, silvery, or red patches of skin.

The Blue Light Therapy Illuminator that will be used in this study (BLU-U Model 4170) is currently FDA approved for the treatment of acne but not for Grover's or psoriasis. Blue light has been used to treat forms of dermatological conditions including skin cancer and acne vulgaris;

however, it's role in treating your condition is unclear. Two previous studies have used blue light in psoriasis and have shown improved outcomes. However, those studies did not examine the skin underneath the microscope or evaluate systemic inflammatory markers (chemicals that indicate disease causing cells) in the blood. Blue light therapy can potentially benefit the amount of redness that is seen in psoriasis vulgaris. In this study, the investigational therapy is blue light because it hasn't been approved for Grover's disease or psoriasis vulgaris.

How long will the research last and what will I need to do?
We expect that you will be in this research study for 5 weeks.

You will be asked to come in for blue light therapy 3 times a week for 5 weeks. We will take 6 biopsies in total (3 on each diseased area, spread over the course of 5 weeks). You will also be asked to give blood 3 times. You will also be asked to take 2 skin quality of life surveys. We will also take photographs of the affected areas a total of 7 times over the course of 5 weeks.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

Blue light: Hyperpigmentation (darker than normal skin) has been a reported side effect of direct blue light therapy.

Biopsies: Presents a small risk for a small scar and infection.

Blood draw: The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting.

Withholding Skin Treatments: Because we are trying to see how well blue light therapy works by itself, we are asking patients not to use systemic medication or treatments for their skin, on the location we treat with Blue Light, for two weeks before this study and for the duration of the study. This may cause symptoms to be worse or more uncomfortable for some time.

Surveys: Some questions may make patients uncomfortable or upset. Patients do not have to answer these questions if they do not want to.

Photographs: Faces will be obscured, but there is a possibility that subjects may be able to be identified from the photographs that will be taken for the study.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include blue light therapy can potentially benefit the amount of redness that is seen in psoriasis vulgaris. The benefits from blue light therapy may not continue after the research has ended.

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What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 312-503-5907.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 20 people here in this study

What happens if I say "Yes, I want to be in this research"?
You will be asked to come to the Northwestern Medical Group Dermatology Clinic, located at 676 N. St. Clair Street, Suite 1600, Chicago, IL 60611. From this point forward, this location will be referred to as the "study site".

A member of the research staff will go in depth with the study with you and outline the study schedule listed below. They will obtain your understanding of the study and obtain an informed consent. At that time, the researcher will schedule the future study appointments with you. In order to take part in this research study, you must also agree to participate in the Dermatology Tissue Acquisition and Biorepository study (STU00009443). You will be asked to read and sign the Dermatology Tissue study consent form. If you choose not to participate in the Dermatology Tissue study, you will not be eligible to participate in this study.

Procedures in this study

The blue light phototherapy: Involve receiving 16 minutes of blue light therapy over the affected area of the body. You will be sitting down and we will use the Blue-U, Blue Light Photodynamic Therapy Illuminator to deliver the dosage of blue light.

Biopsy: Involves receiving a removing a small area of skin, about as big as a pencil eraser using a circular instrumenton the location of Grover's disease or psoriasis vulgaris. This area will be anesthecised first and the area will be closed using stiches or gel foam and may cause small scarring after healed.

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Biopsies are performed a maximum of three times throughout the study so researchers may examine lesional areas under a microscope.

Blood draws: Include drawing around up to 30 cc (about 1-2 Tablespoons) of blood. Blood draws are performed to look for specific cells that cause Grovers Disease and Psorisis that circulate in the bloodstream.

Psychometric and Skin Quality of Life survey: Involves answering questions about the quality of your skin and your thoughts on receiving blue light therapy as treatment.

Photographs of afflicated skin area: Involve taking images of your skin lesions with research-purpse only devices and saving them to secure locations.

Procedure Table

	Blue Light Phototherapy	Biopsy	Blood Draw	Psychometric and Skin QoL survey	Photographs of afflicted skin area
Visit 0 - Consent					X
Visit 1 - Baseline	X	X	X	X	X
Visit 2	X				
Visit 3	X				X
Visit 4	X				
Visit 5	X				
Visit 6	X				X
Visit 7	X	X	X		
Visit 8	X				
Visit 9	X				X
Visit 10	X				
Visit 11	X				
Visit 12	X				X
Visit 13	X				
Visit 14	X				

Visit 15	X	X	X	X	X
Early completion (lesions completely resolve)	X	X	X	X	X

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to:

1. Come to the scheduled appointment visits.
2. If unable to come to a scheduled appointment, you may contact the study team and schedule the appointment for another time.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you. If you decide to leave the research, contact the investigator so that the investigator can remove you from the study and cancel future appointments.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Detailed Risks: Is there any way being in this study could be bad for me?

This research may hurt you in the following ways:

Blue light: Hyperpigmentation (darker than normal skin) has been a reported side effect of direct blue light therapy. (investigational treatment)

Biopsies: Present a small risk for a small scar and infection.

Blood draw: The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting.

Withholding other Skin Treatments: : Because we are trying to see how well blue light therapy works by itself, we are asking patients not to use systemic therapies or treatments on the area of skin we treat in this study, for two weeks before this study and for the duration of the study. This may cause symptoms to be worse or more uncomfortable for some time.

Survey: Some questions may make patients uncomfortable or upset. Patients do not have to answer these questions if they do not want to.

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Photographs: Faces will be obscured, but there is a possibility that subjects may be able to be identified from the photographs that will be taken for the study.

In addition to these risks, this research may hurt you in ways that are unknown.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Data Sharing
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you do not attend the scheduled appointments. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

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What else do I need to know?
If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you $50 per visit for those each visit involving a biopsy and $25 per visit for all other visits involving blue light therapy, and for up to a total of $450.

The Accounting Services at Northwestern University will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

You will not be informed of the results of the research

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical/dermatological history
- Prior and current dermatological treamtments
- Age
- Gender
- Previous Psoriasis Area and Severity Index (PASI) scores
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires

This consent will not expire unless you revoke your consent. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When

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a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- T-Cellerate, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

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Unless you revoke your consent, it will NOT expire

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Shuai Xu, MD MSc
Institution: Northwestern University
Department: Dermatology
Address: 676 N. St. Clair Suite 1600, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

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Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent