ANCILLARY REVIEWS

Which ancillary reviews do I need and when do I need them? Refer to HRP-309 for more information about these ancillary reviews.			
Select yes or no	**Does your study…**	*If yes…*	***Impact on IRB Review***
☐ **Yes** ☑ **No**	Include Gillette resources, staff or locations	*Gillette Scientific review and Gillette Research Administration approval is required. Contact: research@gillettechildrens.com*	**Required prior to IRB submission**
☑ **Yes** ☐ **No**	Involve Epic, or Fairview patients, staff, locations, or resources?	*The Fairview ancillary review will be assigned to your study by IRB staff Contact:* ancillaryreview@Fairview.org	**Approval must be received prior to IRB committee/ designated review.** **Consider seeking approval prior to IRB submission.**
☑ **Yes** ☐ **No**	Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection?	*The regulatory ancillary review will be assigned to your study by IRB staff Contact: medreg@umn.edu* *See: https://policy.umn.edu/research/indide*	
☐ **Yes** ☑ **No**	Require Scientific Review? Not sure? See guidance on next page.	*Documentation of scientific merit must be provided. Contact: hrpp@umn.edu*	
☐ **Yes** ☑ **No**	Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco?	*Complete the CPRC application process. Contact: ccprc@umn.edu*	
☐ **Yes** ☑ **No**	Include the use of radiation? (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy)	*Complete the AURPC Human Use Application and follow instructions on the form for submission to the AURPC committee. Contact: barmstro@umn.edu*	**Approval from these committees must be received prior to IRB approval;**
☐ **Yes** ☑ **No**	Use the Center for Magnetic Resonance Research (CMRR) as a study location?	*Complete the CMRR pre-IRB ancillary review Contact: ande2445@umn.edu*	

☐ **Yes** ☑ **No**	Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents?	*Complete the IBC application via eprotocol.umn.edu* *Contact:*	**These groups each have their own application process.**
☐ **Yes** ☑ **No**	Include the use of human fetal tissue, human embryos, or embryonic stem cells?	*Contact OBAO for submission instructions and guidance*	
☑ **Yes** ☐ **No**	Include PHI or are you requesting a HIPAA waiver?	*If yes, HIPCO will conduct a review of this protocol.* *Contact: privacy@umn.edu*	
☐ **Yes** ☑ **No**	Use data from the Information Exchange (IE)?	*The Information Exchange ancillary review will be assigned to your study by IRB staff* *Contact: ics@umn.edu*	**Approval must be received prior to IRB approval.** **These groups do not have a separate application process but additional information from the study team may be required.**
☐ **Yes** ☑ **No**	Use the Biorepository and Laboratory Services to collect tissue for research?	*The BLS ancillary review will be assigned to your study by IRB staff.* *Contact: cdrifka@umn.edu*	
☐ **Yes** ☑ **No**	Have a PI or study team member with a conflict of interest?	*The CoI ancillary review will be assigned to your study by IRB staff* *Contact: becca002@umn.edu*	
☑ **Yes** ☐ **No**	Need to be registered on clinicaltrials.gov?	*If you select "No" in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff* *Contact: kmmccorm@umn.edu*	
☑ **Yes** ☐ **No**	Require registration in OnCore?	*If you select "No" or "I Don't Know" in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff* *Contact: oncore@umn.edu*	**Does not affect IRB approval.**

Protocol Title	Cleansing device for the treatment of scalp and hair conditions
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	Current Academic Status (Student, Fellow, Resident): Research Fellow
	Department: Dermatology
	Telephone Number: (612) 250-6342
	Institutional Email Address: raymo272@umn.edu
Scientific Assessment	I believe Scientific Assessment is not required.
IND/IDE # (if applicable)	N/A (non-significant risk IDE)
IND/IDE Holder	Ronda Farah, MD (PI)
Investigational Drug Services # (if applicable)	N/A
Version Number/Date:	Version 6, 12 January 2023

PROTOCOL COVER PAGE

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	September 13, 2021	Addition of study members, addition of study visit location, and utilization of paper consent forms. Addition of the Venus Glow device for suction.	Yes
2	February 7, 2022	Addition to the recruitment process, providers may hand out flyers to interested participants at the time of clinic visits.	No
3	April 1, 2022	Change of inclusion criteria to include all individuals 18 years of age or older.	Yes
4	August 14, 2022	Addition of study members, additions to the recruitment process, clarification on randomization, addition of a surgical marker for photography comparison purposes, modification to device.	Yes
5	January 12, 2023	Modification to the device description and clarification of study procedures.	No

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ABBREVIATIONS/DEFINITIONS

Abbreviation	Word or Phrase	Definition
ASFS	Adherent Scalp Flaking Score	An assessment used to quantitate the severity of scalp flaking.

1.0 Objectives

1.1 Purpose: The objective of this study is to evaluate an improvement of scalp health after the use of an investigational off-label WaterPik and brush device aimed to massage and cleanse the scalp.

2.0 Background

2.1 Significance of Research Question/Purpose:

Seborrheic dermatitis and dandruff are skin conditions that present with common features and respond similarly to treatments. Dandruff involves flaking skin that can cause irritation and itching. Dandruff only involves the scalp, whereas seborrheic dermatitis can occur on the scalp, face, chest, and retro-auricular areas (1). Seborrheic dermatitis can also result in itching and flaking, as well as inflammation and erythema (1).

Both dandruff and seborrheic dermatitis are known to be harmful to the scalp. Despite shampoo and washing, one may still continue to have flaking and scale present on the scalp. There are numerous scalp massages and brushes on the consumer market.

Through the investigational use of the off-label WaterPik and brush device, we propose the technique of massage and gentle water pressure will reduce seborrheic dermatitis and dandruff on the scalp.

2.2 Preliminary Data: N/A

2.3 Existing Literature: N/A

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome: The primary endpoint will be physician assessment with the Adherent Scalp Flaking Scale (ASFS). Our hypothesis is that there will be a decrease from baseline in the ASFS within each of the groups.

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s): Secondary endpoints include photography comparisons with the HairMetrix device and global images. Additionally, expert assessment of the subject's scalp after treatment will be performed using the Erythema score and patients will complete a Patient Sensory Assessment of Scalp & Hair.

4.0 Study Intervention(s)/Investigational Agent(s)

4.1 Description:

Waterpik® was FDA approved in 2018 to provide pressured water combined with a powered toothbrush for optimal plaque and particle removal when cleaning the mouth and teeth. Waterpik® now has several products on the market designed for oral health, pet care, and washing in the shower.

Our off-label design utilizes the Waterpik® device, but with adjustments optimized for scalp health. The device settings are adjustable during the treatment, ranging from settings of 2-10. The suction being used for the device has been upgraded to a shopvac and can be modified using a transformer. A small section was cut out of the distal portion of the shopvac hose to place the head of the Waterpik. The Waterpik is housed in a silicone cup to contain the water spray and assist with suction.

4.2 Drug/Device Handling:

The off-label use of the Waterpik device in this protocol meets the following criteria for NSR-IDE. It is not an implant and does not present a potential for serious risk to the health, safety, or welfare of a subject. It is not purported and will not be represented to be for use supporting or sustaining human life and dose not present a potential for serious risk to the health, safety, or welfare of a subject. The device will not be used of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does not present a potential for serious risk to the health, safety, or welfare of a subject. The device does not otherwise pose a potential for serious risk to the health, safety, or welfare of a subject.

The off-label Waterpik device will be stored in the locked research storage room in the Department of Dermatology at the University of Minnesota. Additional supplies will be stored separately in the Department of Dermatology.

While wearing gloves, the device and treatment room will be wiped down with disinfectant wipes after each use. The distal end of the device will be changed in between each subject visit. Gloves, masks, and face shields will be utilized by the study staff that is administering the treatment. Participants will be asked to follow the current CDC guidelines regarding COVID-19.

4.3 Biosafety: N/A - The research does not involve a recombinant or synthetic nucleic acid, human gene transfer, biologically derived toxin, or an infectious agent.

4.4 Stem Cells: N/A - The research does not involve stem cells.

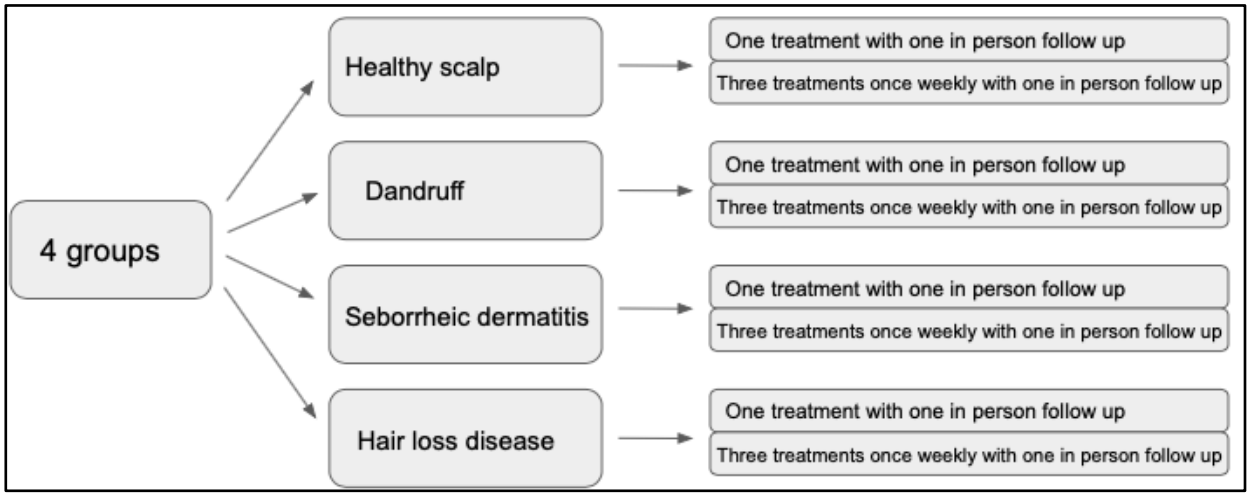
4.5 Fetal Tissue: N/A - The research does not involve fetal tissue.

5.0 Procedures Involved

5.1 Study Design: This is a cohort research study utilizing photography, physician assessments, and subject assessments to evaluate the efficacy of a WaterPik and brush technique in the management of scalp scale. Participants who presently have one of the four conditions: healthy scalp, dandruff, seborrheic dermatitis, or hair loss disease will be followed over a period of 4 weeks to see how well the investigational device works.

Total Enrollment (N= 40): A total of 40 subjects, males and females or other, ages 18+, will be enrolled in the study. The subjects will be placed into a group depending on their scalp condition (Figure 1). The study will have four groups: healthy scalp, dandruff, seborrheic dermatitis, and hair loss disease. Each of the four groups will consist of 10 subjects. Subjects within each group will then be randomly assigned to one of the two subgroups of 5 patients (1 vs 3 treatments). We will use stratified block randomization to assign the treatment of 1 or 3 treatments within each of the 4 scalp groups. We will use random block sizes of 2 and 4 to decrease the chance of predictability of assignment, as well as to ensure approximately equal sample sizes of treatment groups with each of the scalp groups.

Figure 1



5.2 Study Procedures:

Subjects will come into each visit with their scalp and hair not wet. A dry scalp is required for initial photography and assessment purposes. Study staff will take both HairMetrix and global photography prior to subjects receiving the scalp treatment. Study staff will use the Waterpik® device and brush for up to 30 minutes on the subject's scalp until all scale and other debris appears to be resolved. Their scalp will, and re-photographed with the HairMetrix device and global photography. Subjects' scalps will be assessed using the ASFS before and after treatment. Additionally, subjects' scalps will be assessed after treatment using the Erythema score.

HairMetrix images will be taken at three sites during each photography session: frontal anterior scalp (unique to each participant, at the beginning of the hairline), crown (24 cm), and occipital scalp (30 cm). For disease scalp, disease areas will also be photographed as needed. Measurements will be taken from the glabella to each photography site for comparison purposes. Additionally, for comparison purposes, a purple surgical marker will be utilized to mark the subject's scalp each

photography site. The purple surgical marker typically self-removes within a few days.

5.3 Study Duration: The total duration of participant participation will be approximately 4 weeks. The duration anticipated to enroll all study participants is expected to be approximately 3 years. It is anticipated that it will take just over 3 years to complete all study procedures including data analysis.

Week 0 - Baseline/First Treatment	● Consenting and enrollment ● Demographic information ● Medical history ● Subjects to fill out their average shampoo and conditioning regimen in the last 4 weeks, including: o Number of days prior to last shampooing o Name of products o Any products that they have used on their hair/scalp since their last shampoo (oils, sprays, gels, etc.) ● Scalp characteristics on initial arrival of subject ● Patient Sensory Assessment of Scalp & Hair ● Global Photography ● Scalp treatment with the Waterpik® device and brush ● HairMetrix Images before and after treatment ● Expert assessment using the Adherent Scalp Flaking Score before and after treatment ● Expert assessment of the subject's scalp using the Erythema score before and after treatment ● Patient rated pain after treatment, scale 1-10
Week 1 - Second Treatment (+/- 5 days)	● Participant report of adverse events ● Subjects to fill out their average shampoo and conditioning regimen in the last 4 weeks, including: o Number of days prior to last shampooing o Name of products

	○ Any products that they have used on their hair/scalp since their last shampoo (oils, sprays, gels, etc.) ● Scalp characteristics on initial arrival of subject ● Patient Sensory Assessment of Scalp & Hair ● Global Photography ● Scalp treatment with the Waterpik® device and brush ● HairMetrix Images before and after treatment ● Expert assessment using the Adherent Scalp Flaking Score before and after treatment ● Expert assessment of the subject's scalp after treatment using the Erythema score ● Patient rated pain after treatment, scale 1-10
Week 2 - Third (final) Treatment **(+/- 5 days)**	● Participant report of adverse events ● Subjects to fill out their average shampoo and conditioning regimen in the last 4 weeks, including: ○ Number of days prior to last shampooing ○ Name of products ○ Any products that they have used on their hair/scalp since their last shampoo (oils, sprays, gels, etc.) ● Scalp characteristics on initial arrival of subject ● Patient Sensory Assessment of Scalp & Hair ● Global Photography ● Scalp treatment with the Waterpik® device and brush ● HairMetrix Images before and after treatment ● Expert assessment using the Adherent Scalp Flaking Score before and after treatment ● Expert assessment of the subject's scalp after treatment using the Erythema score ● Patient rated pain after treatment, scale 1-10

For all groups and varying treatment lengths, each patient will have a final 1 week follow up visit after their treatment(s) have been completed. Each follow up visit will

include global photography, HairMetrix images, Scalp characteristics, and Patient Sensory Assessment of Scalp & Hair. This follow up visit will be compensated. If a patient happens to miss a study visit, one of the study staff will reach out to the patient via a phone call.

5.4 Use of radiation*:* N/A

5.5 Use of Center for Magnetic Resonance Research*:* N/A

6.0 Data and Specimen Banking

6.1 Storage and Access: Deidentified data may be banked in the University's Box Secure Storage or REDCap database.

6.2 Data: Deidentified data may be banked for future analyses and compilation into larger datasets, such as clinical and demographic information and clinical assessments and rating scales.

6.3 Release/Sharing: Deidentified data from this study may be used in the future to compile larger datasets from multiple studies with similar methodologies and populations to conduct additional analyses and publications. Should the investigators pursue this, future studies seeking to compile data acquired from this protocol will obtain IRB approval before doing so. In the event that this occurs, only investigators or study personnel listed in an IRB-approved protocol pertaining to the data compilation will have access to this data.

7.0 Sharing of Results with Participants

7.1 The individual results of the study will not be shared with participants or others. Deidentified data and images will be compiled, analyzed, and summarized for journal publication and/or poster presentations.

7.2 Sharing of genetic testing:

7.2.1 Disclosure of results: N/A

7.2.2 If returning results to participants: N/A

- Aggregate or individual results: N/A
- Laboratory results: N/A
- Plan for return of results to participants: N/A
- Types of results to be returned to participants: N/A

7.2.3 Future analysis of genotypes: N/A

8.0 Study Population

8.1 Inclusion Criteria:

Participants must meet all of the inclusion criteria.

- All individuals 18 years of age or older

- Participants must qualify for one of the following scalp conditions based on clinical opinion of a board-certified dermatologist:
    - Healthy scalp
    - Dandruff
    - Seborrheic dermatitis
    - Hair loss disease
- Ability to understand study procedures and to comply with them
- All Women of Child Bearing Potential (WOCBP) must indicate use of two of the following contraception methods. The WaterPik device uses an ultrasonic technology which includes ultrasound. Unnecessary ultrasound is not recommended for pregnant women.
    - Use a highly effective method of birth control
        - Combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation:
            - Oral
            - Intravaginal
            - Transdermal
        - Progestogen-only hormonal contraception associated with inhibition of ovulation:
            - Oral
            - Injectable
            - Implantable
        - Intrauterine device (IUD)
        - Intrauterine hormone-releasing system (IUS)
    - Vasectomized partner
    - Sexual abstinence
    - Barrier method, such as a condom

8.2 Exclusion Criteria:

All candidates meeting any of the exclusion criteria at baseline will be excluded from participation in this study.

- Non-English speakers
- Exclusion related to pregnancy, lactation, or has plans to become pregnant over the course of the study

- Based on self-report from the participant
- The WaterPik device uses an ultrasonic technology which includes ultrasound. Unnecessary ultrasound is not recommended for pregnant women.

- Current clinical condition that, in the opinion of the site investigator, would interfere with adherence to study requirements
- Inability or unwillingness of individual or legal guardian/representative to give written informed consent

8.3 Screening: Adult patients in the Department of Dermatology at the M Health Fairview Clinics and Surgery Center or M Health Fairview Maple Grove Clinic will be approached to determine their interest in the study. Dermatologists, Dr. Hordinsky and Dr. Farah, will identify patients that may benefit from scalp cleansing. The study will be introduced after the patient's clinical visit and contact information will be provided if they are interested. Participants may self-refer if they become aware of the study through recruitment materials or word of mouth referrals. Individuals who respond to the recruitment materials will be taken through a phone screening questionnaire. Interested patients will be screened for eligibility using the inclusion and exclusion criteria and written informed consent will be obtained from eligible patients at the baseline visit. Following the screening process, the patient will be seen for their baseline/first treatment visit (see section 5.3 for an outline of study procedures that occur at the baseline visit).

9.0 Vulnerable Populations

9.1 Vulnerable Populations:

Population / Group	Identify whether any of the following populations will be targeted, included (not necessarily targeted) or excluded from participation in the study.
Children	No
Pregnant women/fetuses/neonates	No
Prisoners	No
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	No

Non-English speakers	No
Those unable to read (illiterate)	No
Employees of the researcher	No
Students of the researcher	No
Undervalued or disenfranchised social group	Included / not targeted
Active members of the military (service members), DoD personnel (including civilian employees)	Included
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	No
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	Included / not targeted
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	No
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	No
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	No

9.2 Additional Safeguards: Undervalued or disadvantaged people may not be known, research staff will not be asking a direct question about socioeconomic status to potential participants. We do not anticipate vulnerability for this group to be increased by participating in this study. Additionally, members of the military may not be known, research staff will not be asking a direct question about military status to potential participants. We do not anticipate vulnerability for this group to be increased by participating in this study.

10.0 Local Number of Participants

10.1 Local Number of Participants to be Consented: 40 participants are needed for data analysis and we anticipate needing to consent 55 people to reach that goal.

11.0 Local Recruitment Methods

11.1 Recruitment Process:

If a potential participant is identified at the Department of Dermatology at the University of Minnesota Clinics and Surgery Center or Maple Grove Clinic, and the potential participant has NOT opted out of research, the attending provider will briefly introduce the study and provide a recruitment flyer to the potential participant. The provider will then ask if a member of the study team may come in to talk with them. If the potential participant agrees, the investigator and/or study coordinator will describe the study in detail, answer any questions the potential participant may have and describe next steps. All investigators and study staff will be trained in privacy and confidentiality requirements for conducting research at Fairview facilities. Patients who have opted out of research in their medical record will not be approached.

Additionally, public recruitment will be done via the use of flyers in buildings on the University of Minnesota campus. These buildings could include the Malcolm Moos Health Sciences Tower, Phillips-Wangensteen building, Molecular and Cellular Biology building, and Jackson Hall. The study will also be posted on the University of Minnesota Department of Dermatology website: https://med.umn.edu/dermatology/research/clinical and clinicaltrials.gov. Participants may self-refer if they become aware of the study through these recruitment materials or word of mouth referrals. Individuals who respond to the recruitment materials will be taken through a phone screening questionnaire. If following the phone screen the potential participant is eligible and interested, the study coordinator will schedule the screening study visit.

11.2 Identification of Potential Participants: Potential participants will be identified by the investigators from among patients under their care. Investigators will make the initial contact with potential participants at the time of their clinic visit. Investigators may provide a recruitment flyer to the potential participant.

11.3 Recruitment Materials: Public recruitment will be done via the use of flyers that include the study and contact information. Tabs will be available at the bottom of the flyer to take if interested. Flyers will be posted in buildings on the University of Minnesota campus. Flyers and handouts that include study information may also be handed out to potential participants during clinic visits with the investigators. These buildings could include the Malcolm Moos Health Sciences Tower, Phillips-Wangensteen building, Molecular and Cellular Biology building, and Jackson Hall.

11.4 Payment:

- Subjects will be given compensation for engagement in the study. Total compensation for subjects varies depending on how many study visits they attend. Subjects will receive $30.00 for their baseline study visit at which time they will receive their first treatment. Subjects will receive $20.00 for each additional visit, up to three follow up visits. Subject total compensation can range from $30.00 to $90.00.
- Parking will be provided for all subjects. If the study visit is completed at the M Health Fairview Maple Grove Clinic, no parking vouchers will be necessary because there is no cost of parking at this site. If the study visit is completed at the University of Minnesota Department of Dermatology in the Phillips-Wangensteen building, parking vouchers for the Delaware patient visit parking ramp will be provided to participants.

12.0 Withdrawal of Participants

12.1 Withdrawal Circumstances: Participation in this study is voluntary. Participants are free to withdraw at any time. Investigators may also withdraw participants from the study if participants fail to adhere to the study protocol requirements. Possible withdrawal circumstances may also include: the participant no longer meets the inclusion/exclusion criteria, the participant is lost to follow up, or it is in the participant's best interest to withdraw from the study, as determined by the PI.

12.2 Withdrawal Procedures: Data collection of withdrawn participants will be collected up to the point of withdrawal. Data from withdrawn participants will not be included in the analysis.

12.3 Termination Procedures: This study may be suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension. The study team will also notify the participants of the study termination. Data will not be used after termination. Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

13.0 Risks to Participants

13.1 Foreseeable Risks:

Potential risks include scalp irritation, redness, headache, itching, tingling, and abrasion of the skin.

Privacy/Confidentiality Risks: There is always the slight risk of loss of confidentiality of the medical record information and associated privacy of the participants. These risks will be minimized by storing data securely as per UMN institutional guidelines and limiting access to information contained within the registry to trained UMN investigators and members of the research team.

13.2 Reproduction Risks: N/A

13.3 Risks to Others: N/A

14.0 Potential Benefits to Participants

14.1 Potential Benefits: Participants may experience an improvement in scale, seborrheic dermatitis, and/or oiliness of the scalp, as well as scalp symptoms such as erythema, itching, and burning. Additionally, society and investigators will benefit from the knowledge gained.

15.0 Statistical Considerations

15.1 Data Analysis Plan:
The primary outcome will be ASFS and we will use a paired t-test among all 40 subjects to compare the baseline and post final treatment ASFS scores. Secondary outcomes are Hairmetrix images, global photography, scalp erythema and flaking score, scalp characteristics, Patient Sensory Assessment of Scalp & Hair, and safety measures, and we will use a paired t-test or McNemar's test, or the appropriate non-parametric test if necessary.

As a secondary analysis, we will determine if the change in any of these outcomes significantly differs between the four scalp groups. To do so, we will use linear regression with an effect for group, while adjusting for the baseline outcome value. To account for the multiple group comparisons, we will use a Tukey's post hoc adjustment. We will also perform a paired t-test or McNemar's test to compare the change in outcome at each of the time points to determine the pattern over time.

15.2 Power Analysis:
While this is a pilot study and a power analysis is not strictly necessary, using a paired t-test with an n of 40 and an alpha of 0.05 will lead to 80% power to detect an effect size of 0.45 for the primary outcome of change in ASFS scores. Thus this study should be well powered to detect moderate effect sizes.

15.3 Data Integrity:

- The study monitor will ensure that the investigation is conducted according to protocol design and regulatory requirements. The monitor will provide ongoing monitoring of data validity and regulatory issues

(e.g., eligibility determinations, consent form process, serious adverse event reporting, IRB actions, disclosures of conflict of interest).

- Study records will be monitored at regular intervals by the study monitor. The monitor will perform source data verification and as such must be given access to the subject's primary source documentation, such as paper or electronic medical records such as consent to participate in the study, visit dates, demographic information, medical history, physical examination, vital signs, copies of laboratory reports, adverse events, concomitant medications, drug accountability, etc.) that support data entries in the CRF.
- The PI will be provided copies of monitoring reports shortly after the monitoring visit. Findings will be noted and followed up in the subsequent monitoring visit.

16.0 Health Information and Privacy Compliance

16.1 Select which of the following is applicable to your research:

☐ My research does not require access to individual health information and therefore assert HIPAA does not apply.

☑ I am requesting that all research participants sign a HIPCO approved HIPAA Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

16.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

☑ I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

☐ Other.

16.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

Patients who have opted out of research in their medical record will not be approached to participate in the study.

16.4 Approximate number of records required for review: N/A

16.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☑ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

☑ Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants.

Participants may self-refer if they become aware of the study through these recruitment materials or word of mouth referrals. Individuals who respond to the recruitment materials will be taken through a phone screening questionnaire.

16.6 Explain how the research team has legitimate access to patients/potential participants:

If a potential participant is identified at the Department of Dermatology at the University of Minnesota Clinics and Surgery Center or Maple Grove Clinic, and the potential participant has NOT opted out of research, the attending provider will briefly introduce the study and ask if a member of the study team may come in to talk with them. If the potential participant agrees, the investigator and/or study coordinator will describe the study in detail, answer any questions the potential participant may have and describe next steps. All investigators and study staff will be trained in privacy and confidentiality requirements for conducting research at Fairview facilities.

16.7 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐ In the data shelter of the Information Exchange (IE)

☐ Store ☐ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store ☐ Analyze ☐ Share

☑ In REDCap (recap.ahc.umn.edu)

☑ Store ☑ Analyze ☑ Share

☐ In Qualtrics (qualtrics.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐ In OnCore (oncore.umn.edu)

☐ Store ☐ Analyze ☐ Share

☑ In the University's Box Secure Storage (box.umn.edu)

☑ Store ☑ Analyze ☑ Share

☐ In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

☐ Store ☐ Analyze ☐ Share

☐ In an AHC-IS supported desktop or laptop. Provide UMN device numbers of all devices:

☐ Store ☐ Analyze ☐ Share

☐ Other. Describe:

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐I will use a server not previously listed to collect/download research data

☐I will use a desktop or laptop not previously listed

☐I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

16.8 Consultants. Vendors. Third Parties: N/A

16.9 Links to identifiable data: All data will be identified with an identification code unique to the participant. Study staff will keep the mapping of identification code to the identity of the participant on an encrypted password protected computer

stored separately from the data in the University's Box Secure Storage. That same identification code will be used for data-entry into the REDCap database. Any internal data reports will use only these codes and will not use any identifiable information. Any external data reports, abstracts, publications, presentations, etc. will present de-identified, grouped, and/or aggregate data. Any reports to the University of Minnesota IRB (such as Adverse Event reporting and annual renewal reports) will be kept confidential; they will not include participant- identifiable information; only the participant's identification code will be used.

16.10 Sharing of Data with Research Team Members: Only IRB-approved members of the study team will have access to the data. Data will be shared through REDCap or the University's Box Secure Storage.

16.11 Storage and Disposal of Paper Documents: Consent forms will be stored in locked cabinets at the University of Minnesota Department of Dermatology in the Phillips-Wangensteen building. All other documents will be stored electronically via the REDCap database or the University's Box Secure Storage.

17.0 Confidentiality

17.1 Data Security: Only research staff will have access to subject information. All participant data will be stored in locked cabinets and electronically in REDCap. Passwords will be required to access data in REDCap. Photographs will be stored in the University's Box Secure Storage, and eyes and tattoos will be covered. Study data will be available only to select staff that need access to the information to conduct their research duties. To minimize the volume of documents containing identifying information, all study documents or data will contain a unique participant ID that will be used when possible. No copy of the consent form or other research study information will be placed in the participant's medical, employment, or educational records.

18.0 Provisions to Monitor the Data to Ensure the Safety of Participants

18.1 Data Integrity Monitoring:

Independent monitoring of the clinical study for clinical protocol and IND/IDE application compliance will be conducted by the University of Minnesota's Clinical and Translational Science Institute (CTSI) clinical trial monitoring service. The CTSI monitors will confirm that study activities are in compliance with the approved protocol and applicable regulatory authorities (FDA, IRB, local and State regulations). Frequency of monitoring visits will occur after IRB approval and as soon as possible after the first subject is enrolled, during the study data collection phase and after the last subject has completed his/her participation in the study. Monitoring visits will be performed annually, at a minimum. This monitoring schedule may be revised based on the following considerations:

- Accrual rate

- Protocol deviations or non-compliance with regulatory authorities
- Magnitude of data corrections required
- Study stage (e.g. start-up or follow-up)
- Complexity of the trial
- Request (IRB, Investigator, other etc.)

The sponsor-investigator will permit direct access to the study monitors and appropriate regulatory authorities to the study data and to the corresponding source data and documents to verify the accuracy of these data.

Primary responsibilities of the monitors will include verifying the following:

- Investigator qualifications
- Facilities and equipment
- Storage, dispensing and disposition of investigational products
- Protocol compliance
- Informed consent
- Training and delegation of authority
- Subject eligibility
- Recruitment, screening and enrollment
- Verification of data and data clarification
- Adverse event reporting
- FDA correspondence
- Deviations

18.2 Data Safety Monitoring:

The investigators will ask participants about adverse events at each of the follow-up study visits. Participants are encouraged to call in if they experience any adverse events prior to that time. Study progress and safety will be reviewed monthly (and more frequently if needed) by the PI. The PI will review patient safety data monthly and determine if adverse event rates are consistent with pre-study assumptions, or if there is an increased rate of risk or new information that should be shared with enrolled participants. If a serious adverse event (SAE), Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO), or other event causing risk to the research subjects occurs, the clinical research team will notify the PI immediately. The PI will assure the study is conducted in accordance with the investigator's agreement, the investigational plan, the IDE and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB.

All AEs will be assessed by the study investigators using a protocol defined grading system.

- Mild – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- Moderate – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- Serious – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.
- Related – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- Not Related – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

The Principal Investigator will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

19.0 Provisions to Protect the Privacy Interests of Participants

19.1 Protecting Privacy: The study consent form will describe in detail any intrusive, uncomfortable, or unfamiliar questions, procedures, or interactions with researchers or study personnel that the participant will be asked to complete. Furthermore, the study consent form will communicate that it is the participant's right to opt-out of any study procedures for the study or withdraw from the study at any time and this information will be reiterated and revisited periodically throughout the study in advance of intrusive, uncomfortable, or unfamiliar questions, procedures, or interactions. Participants will not be compelled or pressured to provide information or specimens or study data that they do not wish to provide.

19.2 Access to Participants*:* Participants will be fully informed of the ways in which their data will/may be used during the informed consent process. The research team has been trained in conducting these conversations and the participants are also assessed for their understanding of consent prior to signing the consent form or initiating any study procedures.

20.0 Compensation for Research-Related Injury

20.1 Compensation for Research-Related Injury: If this research activity results in an injury, treatment will be available, including first aid, emergency treatment and

follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to the participant or his/her insurance company.

20.2 Contract Language: N/A

21.0 Consent Process

21.1 Consent Process (when consent will be obtained):

The consent process will take place in a private room at either the M Health Fairview Maple Grove Clinic or the University of Minnesota Department of Dermatology in the Phillips-Wangensteen building. If a patient meets the criteria via the phone screening, we will consent the patient at their baseline visit in person. Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation will be provided to the participants. Consent forms will be approved by the IRB, and the participant will be asked to read and review the document.. The investigator will explain the research study to the participant and answer any questions that may arise. All participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participant will be asked to sign the informed consent document prior to any procedures being done specifically for the study. The participants may withdraw consent at any time throughout the course of the trial. A copy of the informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

21.2 Waiver or Alteration of Consent Process (when consent will not be obtained): N/A

21.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained): We are requesting a waiver of written/signed documentation of consent for the screening portion of this study. A short phone script will be read to the participant before any screening questions are asked. The participant will need to provide verbal consent to answering these screening questions before proceeding. See attached for the screening phone script.

21.4 Non-English Speaking Participants: N/A

21.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): N/A

21.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent: N/A

21.7 Adults Unable to Consent: N/A

22.0 Setting

22.1 Research Sites: Participants will be recruited from the University of Minnesota Maple Grove clinic and the University of Minnesota Clinics and Surgery Center. All study procedures will take place at either the M Health Fairview Maple Grove Clinic or the University of Minnesota Department of Dermatology in the Phillips-Wangensteen building.

22.2 International Research: N/A

23.0 Multi-Site Research: N/A

24.0 Coordinating Center Research

24.1 Role: N/A
24.2 Responsibilities: N/A
24.3 Oversight: N/A
24.4 Collection and Management of Data: N/A

25.0 Resources Available

25.1 Resources Available:

- The dermatology research fellows will be participating in study procedures with the support of the PI. No students will be involved in this study.
- The number of recruitable participants is appropriate for the time period of three years. Forty participants are needed for data analysis and we anticipate needing to consent 55 people to reach that goal.
- One to two hours of PI/study staff time will be dedicated to each visit.
- Facilities for this study include the M Health Fairview Maple Grove Clinic, M Health Fairview Clinics and Surgery Center, and the clinical research room in the University of Minnesota Department of Dermatology in the Phillips-Wangensteen building.
- There are no anticipated severe consequences of the treatment, however, two of the sites are in the clinical setting and one is connected to the UMMC Hospital.
- The PI or Co-PI will be present for all treatments, in addition to dedicated dermatology research staff.