Protocol Title: **The Microbiome of Hidradenitis Suppurativa (HS) Tunneling Wounds**
Protocol Number: **20201035**
Protocol Version #: **1.2**
Protocol Version date: **05May2022**
Principle Investigator Name: **Hadar Lev-Tov, MD**
NCT Number: **NCT04648631**

1) **Objectives***

Our overall hypothesis is that tunneling wound (TW) formation is key in disease progression from local skin disease to systemic inflammatory disease. Further we hypothesize that biofilms present in the TW are detrimental to healing and allow propagation of the disease process. Our specific hypotheses for this project are:
H1: Biofilms exist in HS TW, as determined by microbiome identification and enumeration
H2: antibiofilm treatment can resolve biofilms in HS TW, as determined by microbiome identification and enumeration, histology, or inflammatory and antimicrobial tissue response by host gene expression
H3: treatment of the biofilms in TW modulates the systemic host response.

2) **Background***

Hidradenitis Suppurativa (HS) is a devastating chronic skin disease affecting approximately 1% of the population. Currently, there is no cure for HS. Standard care includes combination of medical and surgical therapies. There is only one agent tested in RCT which provides moderate relief to about half of the patients. As part of disease progression, dermal and subcutaneous tunneling wounds (TW) that communicate with the skin's surface form and are colonized with bacteria.[1] Emerging evidence suggests biofilms form in the TW of HS.[2] Tunnel formation occurs when patients go from locally contained disease to having systemic inflammatory disease and symptoms. While it is generally believed that the skin microbiome participates in the pathogenesis of HS, the presence and the role of biofilms in the cutaneous tunnels has not been well characterized. Additionally, if biofilms exist, eradication of biofilms in the TW may improve HS. We have reported our anecdotal success with treatment of HS TW with antibiofilm surfactant wound gel (ABWG,) (in submission) and we aim to prospectively examine the mechanisms involved.

3) **Inclusion and Exclusion Criteria***

Inclusion criteria

1. Adults 18 years old and older
2. Have diagnosis of HS confirmed by a dermatologist

3. Have at least one HS related tunneling wound that is at least 2 CM in length
4. Able to provide informed consent

Exclusion criteria:

1. Individuals who are not yet adults
2. Women known to be pregnant
3. Prisoners
4. Subjects, who in the opinion of the PI, cannot comply with home application of the treatment.

4) **Number of Subjects***

We intend to recruit 15 subjects.

5) **Study-Wide Recruitment Methods***

Patients with HS seen for their routine care at the Dermatology Outpatient Clinics at the University of Miami Hospital, South Miami satellite site, or Lennar Medical Foundation satellite site will be identified for possible study eligibility by any of the dermatologists in our practice. If the treating dermatologist is a study team member, they will ask the potential subject if they would be interested in being contacted by the study team to learn more about a research study for HS. A partial HIPAA waiver is needed, so that if the patient gives permission to be contacted, they will then be approached by a member of the study team while they are in clinic or if that is not feasible then the treating dermatologist will ask if the patient would like to be contacted by telephone. If the treating dermatologist is not a study team member, they will ask the potential subject to contact the study team for more information by providing the study team's contact information and/or the study flyer. If the potential subject agrees to be contacted by the study team, the treating physician will ask the patient to sign a PHI release authorization form, so that the physician can provide the study team the patient's contact information. If it is then determined that they are interested in participating, they will be scheduled for a visit with the PI at our University of Miami Hospital dermatology clinic site where informed consent and all other study procedures will take place. The risks/benefits of the study will be presented to the subjects, as well as the disclaimer that refusal to participate in the study will in no way, shape, or form alter the type or quality of their care.

A partial HIPAA waiver is also needed as patients diagnosed with HS who signed the University of Miami's Consent to Contact consent during their routine medical care will be identified using research IT and URIDE. Each of those individuals with then be contacted by the phone by a study team member and asked if they would be interested in learning more about a research study on HS. If it is then determined that they are interested in participating, they will be scheduled for a visit with the PI at our

University of Miami Hospital dermatology clinic site where informed consent and all other study procedures will take place. The risks/benefits of the study will be presented to the subjects, as well as the disclaimer that refusal to participate in the study will in no way, shape, or form alter the type or quality of their care.

6) **Study Timelines***

We intend to enroll subjects over a one-year period from the date of IRB approval. Each subject will participate in the study for a total of 4 weeks (28 days +/- 3). Each subject will be invited for 3 visits: initial visit, follow up visit and final visit.

7) **Study Endpoints***

The primary endpoint of the study is the change in microbiome from HS TW before and after 4 weeks treatment with the ABWG as measured by quantitative 16s rDNA PCR for bacterial enumeration.

Secondary outcomes include: Change in lesion severity (as measured by HS-PGA (Table 1) and Hurley Stage (Table 2)), change in pain from baseline (as measured by a 100 mm visual analogue scale), change from baseline in HS lesion erythema as measured by the Clinical Erythema Assessment (CEA) scale (Table 5), change from baseline in exudate graded from none to leaking (see Table 4), changes from baseline in range of motion as measured by a goniometer in the following directions: flexion, extension, abduction, internal and external rotation (Table 6), change in quantity and type of pain medication use, weekly change in number days of work/school lost, number of dressing used per week, Quality of life (using HiSQOL and DLQI).

Other descriptive measures included:

- Microbiome assessment from the tissue using metagenome shotgun sequencing approach to identify all species and their corresponding virulence factors, including genes responsible for biofilm formation antibiotic resistance genes, etc.
- Tissue assessment by histology
- Inflammatory and antimicrobial tissue response by host gene expression before and after treatment for ten representative genes.
- Confocal laser scanning microscopy to visualize and confirm biofilm before and after treatment will be performed on a small subset of subjects (about 5)
- Change from baseline in serum levels of markers of inflammation such as IL-6, IL-8, IL-10, IL-17α, soluble TNF receptor II (sTNF-RII), C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR).

8) **Procedures Involved***

After informed consent is obtained from each subject, they will be invited to participate in the study for 3 visits over 4 weeks. The procedures involved are listed in the table of assessments.

Week	0	+2	+4
Visit	**V1**	**V2**	**V4**
Window (days)	0	±3	±3
Informed consent	X		
Eligibility	X		
Subject ID assignment	X		
Chart review	X		
Demographics	X		
HS history	X		
Medical history	X		
Concomitant medication	X	X	X
Physical exam (focused)	X	X	X
HS lesion map	X	X	X
HS lesion ultrasound	X	X	X
Hurley stage	X	X	X
HS-PGA	X	X	X
Pain (VAS) -General	X	X	X
Pain (VAS) -target TW	X	X	X
Pain medication usage past 3 days	X	X	X
Height	X		
Body weight	X		X
Exudate	X	X	X
Erythema	X	X	X
Range of motion affected joint	X	X	X
Incision and drainage	X		
Product application	X	X	X
Tissue collection	X		X
Serum collection	X		X
QOL	X		X
Work/school days lost	X	X	X
Number of dressing used	X	X	X
Photography	X	X	X
Ease of ABWG application	X	X	X
Adverse events	X	X	X

At the first visit, the medical history will be reviewed and demographics, HS history and concomitant medications will recorded using the medical chart and history given by the patient. Then, the tunnel of interest will be identified and a picture of the lesion will be taken. The first swab of the lesion will be performed and placed in a collection tube labeled with the patient number, date and "pre." The area will be cleaned, then anesthetized using local anesthesia. Once the area is properly anesthetized, a punch incision will be made and the tissue placed in a sterile petri dish lined with gauze labeled with the patient number, date and 1. After the tissue is place in the dish, sterile PBS will be added to the gauze.

A probe will then be inserted into the tunnel to identify the terminal end. A second punch incision will be made at the end of the tunnel and the tissue will be collected in a second sterile petri dish labeled with the patient number, date and 2. Hemostasis will be achieved. Once hemostasis is achieved, a second picture will be taken of the lesion. The ABWG (BlastX, NextScience, Jacksonville, FL) will then be applied to both punch sites using a tongue depressor. Absorbent dressing will be applied to cover the wound.

In the days between visits, patients will apply one fingertip unit of the ABWG to the study wound daily.

In order to correlate the change in microbiome to secondary clinical outcomes, at each visit a focused physical exam will be performed. The corresponding HS-PGA (Table 1) and Hurley Stage (Table 2) will be calculated. The HS lesion locations will be marked on a HS Lesion Body Map (Table 3) and will also be photographed using standard photography.

At each visit, the subject's pain on a *100mm* visual analog scale, amount of pain medication used, number of dressings used, quality of life, and number of work/school days lost will also be quantified. Wound site exudate will be graded based on the Table 4 below. HS lesion erythema will be graded on the Clinical Erythema Assessment (CEA) scale (Table 5) at each visit. Active range of motion in degrees of the nearby joint (shoulder or hip) will be observed and recorded using a goniometer in the following directions: flexion, extension, abduction, internal and external rotation (Table 6). During the first and last visit quality of life will be assessed utilizing the Dermatology Life Quality Index (DLQI) and the HS Quality of Life Questioner (HiSQOL). The DLQI questionnaire is designed for use in adult participants with inflammatory skin diseases and has been used in HS studies. The DLQI surveys participants about symptoms and feelings, daily activities, leisure, work and school, personal relationships and treatment. The DLQI total score ranges 0 -30 (lower scores indicating higher health related QOL). A total score of 0 or 1 indicates no significant impact of the disease on health related QOL. A 4 point change in the DLQI total score has been reported to be a meaningful change in the subject's QOL. The HiSQOL questionnaire is comprised of 17 items and has a recall period of 7 days. The HiSQOL includes 3 subscales: symptom status, psychosocial impact, and impact on physical activities. It has been recently validated and is HS disease specific.

At the last visit, the lesion will be swabbed, and the sample will be collected per the tissue collection protocol above. The patient will then be offered excision of the lesion and that tissue will be collected and sent to the lab, as well.

Data and specimens can be accessed by approved study personnel only.

Table 1: HS PGA Scale

Appendix Table 1. **Hidradenitis Suppurativa Physician's Global Assessment Scale**

Rating	Description
Clear	0 abscesses, 0 draining fistulas, 0 inflammatory nodules, and 0 noninflammatory nodules
Minimal	0 abscesses, 0 draining fistulas, 0 inflammatory nodules, and presence of noninflammatory nodules
Mild	0 abscesses, 0 draining fistulas, and 1–4 inflammatory nodules or 1 abscess or draining fistula and 0 inflammatory nodules
Moderate	0 abscesses, 0 draining fistulas, and ≥5 inflammatory nodules or 1 abscess or draining fistula and ≥1 inflammatory nodule or 2–5 abscesses or draining fistulas and <10 inflammatory nodules
Severe	2–5 abscesses or draining fistulas and ≥10 inflammatory nodules
Very severe	>5 abscesses or draining fistulas

Table 2: Hurley Score

Stage 1 - single or multiple abscesses without sinus tract formation or scarring

Stage 2 - recurrent abscesses with one or more sinus tracts and scarring widely separated by normal skin

Stage 3 - diffuse involvement with multiple sinus tracts and no intervening normal skin

Table 3: Body Map

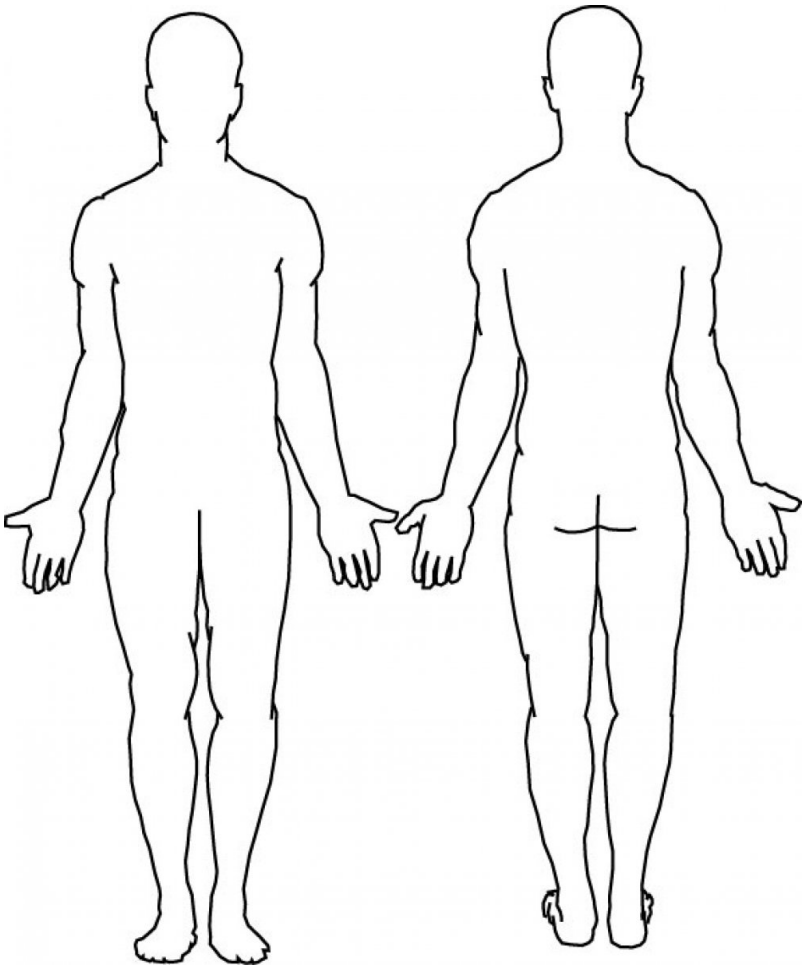

Table 4: Exudate Evaluation

	Indicators		
Status	**Wound bed**	**Dressing**	**Surrounding skin**
Dry	Wound bed is dry; there is no visible moisture	Primary dressing is unmarked; dressing may be adherent to wound	Skin may be scaly, atrophic, hyperkeratotic
Moist	Small amounts of fluid are visible when dressing is removed; wound bed may appear glossy	Primary dressing may be lightly marked; dressing change frequency is appropriate	Skin is likely to be intact, hydrated, no lesions
Wet	Small amounts of fluid are visible when the	Primary dressing is extensively marked, but strikethrough does not	Initial fragmented areas of

	dressing is removed	occur; appropriate dressing change frequency	maceration may be apparent
Saturated	Free fluid is visible when the dressing is removed	Primary dressing is wet and strikethrough occurs; dressing change is required more frequently than usual	Peri-wound skin is likely to be macerated or denuded with extensive involvement
Leaking	Free fluid is visible when the dressing is removed	Dressings are saturated and exudate is escaping from primary and secondary dressings onto clothes or beyond; dressing change is required much more frequently than usual	Peri wound skin is likely to be macerated or denuded with extensive involvement

Table 5: Clinician Erythema Assessment (CEA)

	CEA
0 = Clear	Clear skin with no signs of erythema
1 = Almost clear	Almost clear; slight redness
2 = Mild	Mild erythema, definite redness
3 = Moderate	Moderate erythema; marked redness
4 = Severe	Severe erythema; fiery redness

9) **Data and Specimen Banking***

Study records including informed consents and source documents will be stored in a locked cabinet in the Dermatology Clinical Trials Unit at University of Miami (University of Miami Hospital West Building, 1321 NW 14th St, Suites 504-508, 33136).

Collected samples will be assigned numeric identifiers (subject ID, visit and date of collection). Specimens will be banked for future use and kept under lock in the Pastar laboratory (1600 NW 10th Ave, RMSB 6056, Miami FL 33136). All specimens will be stored at -80°C in the laboratory (1600 NW 10th Ave, RMSB 6056, Miami FL 33136).

10) **Data and Specimen Management**

Data collected will be analyzed by study staff. All study data will be saved on UM computers that are password protected. After initial data collection, all data analyses will be conducted in aggregates and will be de-identified.

11) **Provisions to Monitor the Data to Ensure the Safety of Subjects***

This study involves procedures that are within the standard care spectrum for HS. However, the safety of subjects is the primary objective of the PI and the study staff. All subjects will be evaluated for adverse events routinely at every study visit. PI and study staff will actively solicit relevant adverse events. Subjects will also be provided with contact information and encouraged to contact PI and study staff with any concern or emerging adverse event. Since this is small, unblinded study, a data monitoring committee is not required. Data recorded in the subject's CRF will be reviewed for specific adverse event including: pain, fever, chills, bleeding, burning or discomfort from product application. Since all procedures conducted are within the scope of standard care, we do not expect significant adverse events above and beyond the usual events associated with minimally invasive surgical procedure (i.e. incision and drainage). However, if a subject dies or experiences admission to the hospital due to adverse event that is involving the treatment site or any serious adverse event that is directly related to the study procedure, the PI will pause the study for assessment and decide if to continue the study.

12) Adverse events

Collecting Adverse Events

Study staff and PI are responsible for soliciting, recording and reporting any adverse event during the study period. In addition to unsolicited reports by subjects, the PI and study staff will open every visit by asking for any change in health or any other complaint since the last visit.

Definition of an adverse event

In this study an adverse event (AE) will be defined based on FDA CFR Title 21: "Adverse event means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related" [28]. Therefore an AE is considered as any unplanned medical occurrence that affects subject's health and/or well-

being. The adverse event need not be directly related to the study device or procedure. As such, an adverse event may include any unintended outcome such as a symptom or a new diagnosis or worsening or improvement of existing medical condition.
Serious adverse event (SAE) is defined according to FDA CFR title 21: “Serious adverse event or serious suspected adverse reaction. An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse”.
A SAE is therefore an AE that:

1. Results in death.
2. Is life-threatening at the time of the AE.
3. Results in an inpatient hospitalization or prolongation of existing hospitalization.
4. Results in a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
5. Is a congenital anomaly/birth defect.
6. May require medical or surgical intervention to prevent one of the outcomes listed above.

Documenting and reporting adverse events
All adverse events need to be recorded and reported to the local IRB and the sponsor in a timely manner and in accordance to local regulations.

Assessment of advance event causality
For each AE the PI is responsible for assessing the relationship between study procedure including application of study device and the AE in order to determine causality. The relationship of AE to study activities will be recorded in the AE log. The PI will use the following terms to describe relationship of AE to study activities:
Probable: the AE appears to follow a temporal sequence following study related activities, or has a dose relationship with study activities (i.e. worse when activity increased and visa versa) and cannot be attributed to other causes such as past medical history.
Possible: the AE appears to follow a temporal sequence following study related activities, or has a dose relationship with study activities (i.e. worse when activity increased and visa versa) but could be attributed to other causes such as past medical history and other therapies.

Unlikely: the AE does not appears to follow a temporal sequence following study related activities, and does not demonstrate a dose relationship with study activities (i.e. worse when activity increased and visa versa) and could reasonably be attributed to other causes such as past medical history and other therapies.
Cannot assess: the PI cannot make determination of causality at this time due to insufficient information and/or contradictory or unreliable information. The PI will frequently re-evaluate the AE in order to classify it into one of the classes above.

13) **Withdrawal of Subjects**

Although unlikely, a subject may withdraw from the study at any time at their own request. Subjects may also be withdrawn at any time at the discretion of the PI due to concerns about safety, behavioral, compliance, or administrative reasons.
At the time of discontinuing from the study, visit 3 relevant assessments will be conducted. Subjects will be questioned regarding their reason for withdrawal and reasons will documented in the CRF. If the subject withdraws from the study and also withdraws consent (see below) for disclosure of future information, no further evaluations will be performed, and no additional data will be collected. The PI may retain and continue to use any data collected before such withdrawal of consent. If a subject withdraws from the study due a SAE, the SAE will be recorded in the CRF and reported to the IRB. Lack of completion of all or any of the withdrawal/early termination procedures will not be viewed as protocol deviations so long as the participant's safety was preserved.

Withdrawal of Consent:

Subjects who request to discontinue receipt of study treatment will remain in the study and must continue to be followed per protocol. The only exception to this will be when a subject specifically withdraws consent for any further contact. Subjects should notify the PI or staff of the decision to withdraw consent from future follow-up and this will be recorded in the CRF. The withdrawal of consent should be explained in detail in the CRF, as to whether the withdrawal is only from further receipt of treatments or also from study procedures and/or posttreatment study follow-up.

14) **Risks to Subjects***

The procedures involved in the study are within the standard care for people with HS and are indicated. Therefore, the main added risk we anticipate is unintentional reveal of PHI.

Additional risks that are inherent in the standard care treatment include: pain, bleeding, infection and abnormal scarring that are related to the surgical procedures. There are minimal risks associated with the FDA cleared ABWG that include stinging or burning at the application site.

15) **Potential Benefits to Subjects***

Regardless of the research outcomes, the patients will benefit from immediate symptom relief. They will also have better healing of the lesions. They may also experience no recurrence in the areas treated. If our hypothesis is correct, they will be spared worsening of disease. Given the poor overall management of HS nationwide, patients will benefit from

care at an expert medical center. Patients will also have access to free dressing and wound care for the duration of the study which are infrequently covered for HS.

16) **Vulnerable Populations***

This research study does not include vulnerable populations. Specifically, we will not enroll minors, pregnant women, prisoners, or cognitively impaired people.

17) **Multi-Site Research***

This is a single site study.

18) **Community-Based Participatory Research***

This study was designed without CBPR.

19) **Sharing of Results with Subjects***

There are no results to share with the subjects.

20) **Setting**

Clinical study activities will take place in the Dermatology Clinical Trials Unit at University of Miami (University of Miami Hospital West Building, 1321 NW 14th St, Suites 504-507, 33136) and the Dermatology clinic at UMH (1295 NW 14th St suite K/L/M, Miami, FL 33125).
Laboratory analysis activities will take place in the Pastar laboratory (1600 NW 10th Ave, RMSB 6056, Miami FL 33136). All specimens will be stored at -80°C in the laboratory (1600 NW 10th Ave, RMSB 6056, Miami FL 33136).

This study is open to all eligible subjects. Recruitment efforts will focus on the existing dermatology clinics with the University of Miami Health System as well as other specialty clinics at UMHS where HS subjects may visit such as general surgery, plastic surgery and gynecology.

21) **Resources Available**

Dr. Lev-Tov (PI) is a board-certified dermatologist with extensive experience in treating people with HS and the study related procedures. He has conducted many clinical trials and is considered a leader in the field. Dr. Pastar (co-PI) is an associate professor at UM and well recognized expert in the field of wound healing. She has conducted many similar studies and has all the expertise and equipment needed to conduct the work related to this study.

Both Dr. Lev-Tov and Dr. Pastar will personally train all study staff on the procedures related to the protocol. All study team members will also complete the necessary CITI training modules.

Prior Approvals

No prior approvals are needed.

22) **Local Number of Subjects**

We plan to complete the study on 12 subjects. Given the usual attrition rate we will plan to consent up to 15 subjects.

23) **Confidentiality**

The research team will keep all study information and samples in a locked office and laboratory under password protection while the database is maintained. All data and specimens will be de-identified and coded as described earlier. The data will be only accessible by the research team. Local transport of study specimens will be done in a sealed biohazard bag within a secondary container with a secured lid.

Choose the statements below that are applicable to this research:

26(a). Will the research collect protected health information or personally identifiable information from the EMR or from subjects at UHealth and/or JHS?
☒ Yes (If checked go to 26(b))
☐ No (If checked, go to Section 27)

26(b). Check the box next to the correct statement below
☒ Research Subjects will sign a HIPAA Authorization before the research will collect this data.
☐ Research Subjects will not sign a HIPAA Authorization for this data collection and the research is requesting a waiver of HIPAA authorization from the IRB.

26(c). How will the research store the data?
☒ On a University of Miami electronic device (e.g. encrypted, password-protected computer)
☐ On a cloud-based storage system that is approved by the University of Miami
☐ On the secured JHS SharePoint environment.
☐ Other, specify: Click here to enter text.

26(d) Select one of the following:
☐ The Principal Investigator (and/or Study Team members) will record (e.g. write down, abstract) data acquired in a manner that does not include any indirect or direct identifiers (listed in the instructions for Section 26 of this protocol), and the recorded data will not be linked to the individual's' identity.
OR
☒ The Principal investigator (and/or Study Team members) will record (e.g. write down, abstract) the data collected in a manner that does not include any direct identifiers (see list in the instructions for Section 26 of this protocol) of any subject. Instead, the Principal Investigator and/or Study Team members shall will assign a code (that is not derived in whole or in part from any direct or indirect identifiers of the individual) to

each study subject and link the code to the study subject's identity. The link to each subject's identity and/ or other identifiable information will be maintained on a document separate from the research data.

26(e) Additional requirement for Jackson Health System Data:

Not-applicable, no data will be acquired from JHS under a waiver of authorization.

☐ JHS data, including Protected Health Information (PHI) and/or Personally Identifiable Information (PII), acquired from JHS for this research under a waiver of authorization shall only be stored on the secured JHS SharePoint environment made available by JHS. I and the Study Team members shall not copy or store the JHS sourced personally identifiable information (PII), including protected health information (PHI) data to any other system, including any systems maintained or provided by the University of Miami. I and the Study Team shall only copy or transfer JHS-sourced data that has been properly de-identified in accordance with all requirements contained in the HIPAA Rules by removing all of the identifiers listed in the instructions for Section 26 of this protocol.

27. Biospecimens

☐ Not applicable. No biospecimens will be collected

☐ *Bio*-Specimens obtained for this research will be stored without any direct or indirect identifiers.

☒ *Bio*-Specimens obtained for this research will be stored in a de-identified coded manner.

When required to transport data or bio-specimens for this research, the research team will transport the data and bio-specimens in a de-identified (or anonymous) manner with a link to the individual subject's identity maintain separately from the data and/or bio-specimen.

24) **Provisions to Protect the Privacy Interests of Subjects**

Study subjects will only be asked to provide personal information to approved study personnel, who will ensure the subject is at ease with the situation. Study personnel will clearly explain that the subject does not have to answer any questions or provide any sample they are uncomfortable about

25) **Compensation for Research-Related Injury**

Treatment will be available if enrolled subjects get sick or injured. However, the subject or the subject's insurance will be responsible for

these costs. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not available.

26) **Economic Burden to Subjects**

The study subjects will not have to pay for any procedure involved in the research study.

27) **Consent Process**

The research team will follow the "HRP-090 SOP: Informed Consent Process for Research" to obtain informed consent and the "HRP-091 SOP: Written Documentation of Informed Consent" to document informed consent in writing.

The consent and assent will be translated into Spanish for the inclusion of non-English Spanish speakers.

Study personnel will meet with each potential subject to discuss the study in detail, answer questions, and allow the subject to read the entire consent form. The informed consent form explicitly states the rationale for the study and requirements for participation, both before and during the session. The informed consent form states that subjects may discontinue participation or be terminated from the study at any time.

All pertinent aspects of the study will be explained to the subject before he or she signs the informed consent form. A signed informed consent form will be obtained from the subject before any activity is undertaken as part of the study.

28) **Process to Document Consent in Writing**

The research team will follow the "HRP--091 SOP: Written Documentation of Informed Consent" to document informed consent in writing.

29) **Authorization for Use and Disclosure of Protected Health Information (HIPAA)**

Type of Request:
☒ Waiver of Authorization for access to medical record for subject identification/recruitment.
☐ Waiver of Authorization for access to medical record to obtain data for the research.

Confirm that you will destroy the Protected Health Information (PHI) you and/or your Study Team acquire receive from JHS and/or UHealth at the earliest opportunity.
☒ ***I confirm***

Confirm that the Protected Health Inform (PHI) you acquire from JHS and/or UHealth will not be re-used or disclosed to any other person or entity, except as

required by law or for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible.

☒ ***I confirm***

30) **Drugs or Devices**

All drugs and devices used in the study will be used in a manner consistent with routine clinical practice and "per label". The main study intervention is the use of an anti-biofilm wound gel marketed under the name BlastX. BlastX has been cleared by the FDA for treatment of wounds (see FDA 510 (K) marketing approval letter attached) and will be used "per label" and routine clinical practice.

31) **References**

1. Ring HC, Sigsgaard V, Thorsen J, et al. The microbiome of tunnels in hidradenitis suppurativa patients. *Journal of the European Academy of Dermatology and Venereology : JEADV* 2019; **33**(9): 1775-80.

2. Ring HC, Bay L, Nilsson M, et al. Bacterial biofilm in chronic lesions of hidradenitis suppurativa. *The British journal of dermatology* 2017; **176**(4): 993-1000.