PROTOCOL TITLE:

Sexual function outcomes following periclitoral PRP added to anterior vaginal wall PRP: a randomized controlled trial

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
2	8/3/26	Consistency regarding sham injection without saline throughout protocol and ICF, clarification of three total follow-up visits (6 weeks, 3 months, 6 months), flyer update	Yes
3	9/14/26	Consistency with sexual activity inclusion criteria across documents, clarification of pregnancy as an exclusion criteria, clarification of alternative treatments, clarification of disposal of specimens following procedure.	Yes

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1.0 Study Summary

Study Title	SPARk **S**exual function outcomes following **P**ericlitoral PRP **a**dded to anterior vaginal wall PRP: a **r**andomized controlled trial
Study Design	Single-Blinded Randomized Control Trial
Primary Objective	To evaluate the effect of adjunctive peri-clitoral platelet-rich plasma (PRP) injection on female sexual function in participants undergoing anterior vaginal wall PRP injection.
Secondary Objective(s)	Secondary objectives include assessing the safety and tolerability of peri-clitoral platelet-rich plasma (PRP) injection, evaluating the feasibility of recruitment, retention, participant blinding, and follow-up in a randomized sham-controlled study design, assessing changes in individual domains of female sexual function including desire, arousal, lubrication, orgasm, satisfaction, and pain, evaluating participant satisfaction with treatment, and assessing the durability of changes in sexual function outcomes over the study follow-up period.
Research Intervention(s)/ Investigational Agent(s)	Platelet-rich plasma
IND/IDE #	N/A
Study Population	Adult (18+) natal females who are sexually active with at least one episode of sexual activity in the month prior to study enrollment
Sample Size	58 subjects
Study Duration for individual participants	6 months
Study Specific Abbreviations/ Definitions	FSD – Female Sexual Dysfunction PRP- Platelet Rich Plasma AE – Adverse Event FSFI- Female Sexual Function Index FSDS – Female Sexual Distress Scale PGI-I – Patient Global Impression of Improvement VAS – Visual Analog Scale

2.0 Objectives*

2.1 Describe the purpose, specific aims, or objectives.

The purpose of this study is to evaluate whether adding peri-clitoral platelet-rich plasma (PRP) injection to anterior vaginal wall platelet-rich plasma injection significantly improves sexual function compared with anterior vaginal wall platelet-rich plasma injection alone. Female sexual dysfunction is common, multifactorial, and undertreated. Prior randomized trial data from the Medstar institution suggests that anterior vaginal wall PRP may improve sexual function (Clarke et al., 2026, aka the VIP trial); however, in practice providers frequently perform PRP injection in the anterior vaginal wall as well the periclitoral tissues. Clarke et al did not include periclitoral injections in their protocol and prior studies including periclitoral PRP have been limited, either to small case series (Runels et al., 2014) or without adjunctive anterior vaginal wall PRP (Aglamis et al., 2025). Thus, the utility and potential adverse effects of PRP injection in periclitoral tissues has not been properly investigated with no high quality data investigating the incremental benefit or risk of adding peri-clitoral PRP injection.

The primary objective is to compare the change in Female Sexual Function Index score from baseline to 6 weeks between participants receiving anterior vaginal wall PRP plus peri-clitoral PRP injections (active) and participants receiving anterior vaginal wall PRP plus peri-clitoral sham injection (control).

Secondary objectives are to evaluate the durability of PRP treatment effect at 3 months and 6 months, compare patient-reported impression of improvement, compare periprocedural pain between groups, and evaluate adverse events.

Secondary outcomes:

1. Change in total FSFI score from baseline to 3 months, 6 months.
2. Change in FSFI subdomain scores, including desire, arousal, lubrication, orgasm, satisfaction, and pain, at 6 weeks, 3 months and 6 months.
3. Proportion of participants achieving a clinically meaningful improvement in FSFI score, defined as an increase of at least 4.05 (Sarebani et al.) points.
4. Proportion of participants exceeding clinically relevant FSFI thresholds, such as FSFI ≥26.55 (defined as the optimal cut score for differentiating women with and without sexual dysfunction).
5. Patient Global Impression of Improvement (PGI-I) scores at 6 weeks, 3 months, and 6 months.
6. Procedural pain measured by visual analog scale approximately 10–15 minutes after injection.
7. Frequency and type of adverse events reported during follow up timeframe

2.2 State the hypotheses to be tested.

The primary hypothesis is that participants randomized to peri-clitoral PRP injection in addition to anterior vaginal wall PRP injection will have greater improvement in sexual function, measured by change in total Female Sexual

Function Index score from baseline to 6 weeks, compared with participants randomized to anterior vaginal wall PRP injection plus peri-clitoral sham injection.

Secondary hypotheses are that participants receiving peri-clitoral PRP will demonstrate greater improvement in Female Sexual Function Index score at 3 months and 6 months, improvement in FSFI subdomain scores, higher Patient Global Impression of Improvement scores, and a similar adverse event profile compared with participants receiving peri-clitoral sham injection. We also hypothesize that peri-clitoral PRP injection will be feasible and tolerable, with procedural pain that is not meaningfully greater than peri-clitoral sham injection.

3.0 Background*

3.1 Describe the relevant prior experience and gaps in current knowledge.

Female sexual dysfunction (FSD) is a highly prevalent condition, affecting approximately 43% of women in the United States, with 23% reporting significant associated distress. Despite its profound impact on quality of life, non-hormonal treatment options remain significantly limited (Shifren et al., 2008). Platelet-rich plasma (PRP), an autologous biologic therapy, has emerged as a potential regenerative solution due to its high concentration of platelets found to release growth factors upon activation (Alsousou et al., 2009). These factors, including vascular endothelial growth factor (VEGF) and platelet-derived growth factor (PDGF), are hypothesized to improve tissue health through mediated angiogenesis, collagen synthesis, and neuro-regeneration of surrounding tissue (Wu et al., 2025).

While the application of PRP in Urogynecology is relatively new, prior randomized data from the V.I.P. trial (Clarke et al., 2026) demonstrated modest improvements in sexual function following PRP injection into the anterior vaginal wall. However, earlier uncontrolled studies (Runels et al., 2014) that incorporated peri-clitoral injections reported larger clinical improvements, suggesting a potential additive effect when targeting the clitoral complex. The clitoris is a multifaceted neurovascular structure, with the glans representing only the external portion of a much larger internal complex of bulbs and crura (O'Connell et al., 2005). Because the clitoral region contains a dense network of nerves and blood vessels essential for arousal and orgasm, it is a high-priority target for regenerative therapy.

To date, the efficacy of peri-clitoral PRP has not been evaluated within a rigorous, randomized controlled design.

3.2 Describe any relevant preliminary data.

The primary preliminary data supporting this study come from the Vaginal Injection of Platelet-Rich Plasma for Sexual Function trial (VIP), which evaluated anterior vaginal wall PRP for female sexual dysfunction. In that randomized trial, participants receiving

anterior vaginal wall PRP demonstrated statistically significant improvement in total Female Sexual Function Index score at 6 weeks and 6 months. Within the PRP treatment arm, statistically significant improvements were observed in several FSFI subdomains, including desire at 6 weeks and arousal, lubrication, and orgasm at both 6 weeks and 6 months. At 6 months, a greater proportion of participants in the PRP arm reported subjective improvement compared with controls.

Additional preliminary evidence comes from small studies and commercial protocols that include peri-clitoral PRP injection, such as the "O-Shot" approach. One small uncontrolled series reported improvement in FSFI scores after localized PRP injections, including peri-clitoral injection, but included only 11 participants, lacked a control arm, and was at high risk for bias. The reported magnitude of FSFI improvement in that study was larger than that observed in the VIP trial, raising the possibility that peri-clitoral injection may contribute additional benefit; however, this remains speculative because the study design did not isolate the peri-clitoral component. That study also reported extreme sexual arousal in two patients, highlighting the need to evaluate safety and adverse events in a controlled manner.

Together, these preliminary data suggest that PRP may have a clinically relevant treatment signal for female sexual dysfunction, but they do not establish whether peri-clitoral PRP adds incremental benefit or risk when combined with anterior vaginal wall PRP.

3.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

Female sexual dysfunction is common, multifactorial, and undertreated. Current therapies have variable efficacy and may not address local tissue-level contributors to arousal, lubrication, orgasm, or genital sensation. Platelet-rich plasma (PRP) is an autologous blood product that concentrates platelets and growth factors, with proposed effects on tissue regeneration, connective tissue synthesis, cellular proliferation, and revascularization.

The VIP trial by Clarke et al., conducted through the MedStar Health Research Institute, is the strongest current evidence supporting PRP for female sexual function. In this single-blind randomized controlled trial, anterior vaginal wall PRP was associated with greater improvement in Female Sexual Function Index scores at 6 weeks and 6 months, higher Patient Global Impression of Improvement scores, and no serious adverse events, though PRP was more painful than saline injection.

However, the VIP trial evaluated anterior vaginal wall injection only. Many commercial PRP protocols also include peri-clitoral injection, but the added benefit and safety of this component are unknown. Clarke et al. noted that prior studies reporting larger FSFI

improvements included peri-clitoral injections, raising the possibility that this injection site may contribute additional benefit.

This study aims to investigate whether adding a approximately 1mL peri-clitoral PRP injection to the standard anterior vaginal wall protocol results in a clinically meaningful improvement. By employing a single-blind, placebo-controlled design, this pilot trial will add to existing knowledge by determining whether peri-clitoral PRP provides incremental improvement in sexual function beyond anterior vaginal wall PRP alone, while also evaluating procedural pain, tolerability, and adverse events.

4.0 Study Endpoints*

4.1 Describe the primary and secondary study endpoints.

The **primary study endpoint** is change in total Female Sexual Function Index (FSFI) score from baseline to 6 weeks after treatment, comparing participants randomized to anterior vaginal wall PRP plus peri-clitoral PRP versus anterior vaginal wall PRP plus peri-clitoral sham injection.

While there is no universally established MCID for the FSFI total score across populations, prior studies have used clinically meaningful change thresholds in the approximate 4–5 point range. Krychman et al. estimated an anchor-based FSFI total-score MCID of ≥4.8 points in the VIVEVE I randomized trial, while Sarebani et al. used a distribution-based method to derive an FSFI total-score MCID of 4.05. For this study, we will define responder status a priori as an increase of ≥4.05 points in FSFI total score, (Krychman et al., 2017, Sarebani et al., 2023, Wiegel et al., 2005).

Secondary study endpoints include:

1. Change in total FSFI score from baseline to 3 months.
2. Change in total FSFI score from baseline to 6 months.
3. Change in FSFI subdomain scores, including desire, arousal, lubrication, orgasm, satisfaction, and pain, at 6 weeks, 3 months, and 6 months.
4. Proportion of participants achieving a clinically meaningful improvement in FSFI score, defined as an increase of at least 4.05 points.
5. Proportion of participants exceeding clinically relevant FSFI thresholds, such as FSFI ≥26.55.
6. Patient Global Impression of Improvement (PGI-I) scores at 6 weeks, 3 months, and 6 months.
7. Procedural pain measured by visual analog scale approximately 10–15 minutes after injection.
8. Frequency and type of adverse events reported during follow-up.

4.2 Describe any primary or secondary safety endpoints.

There is no separate primary safety endpoint. Safety will be assessed as a secondary outcome.

Secondary safety endpoints include:

1. Serious adverse events.
2. Local injection-related symptoms, including bleeding, infection symptoms, abnormal discharge, worsening pain, persistent discomfort, numbness, hypersensitivity, or undesired changes in sexual arousal or genital sensation.
3. Comparison of adverse event rates between the peri-clitoral PRP and peri-clitoral sham groups at 6 weeks, 3 months, and 6 months.

Because the peri-clitoral region is highly vascular and innervated, safety assessment will specifically focus on pain, bleeding, infection, sensory changes, and unexpected sexual arousal or discomfort after injection.

5.0 Study Intervention/Investigational Agent

1.1 Description: *Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.*

Platelet-rich plasma is a substance derived from the participants' own blood and is not considered a drug. It is created through centrifugation of a participant's whole blood to separate out red blood cells leaving a concentrated plasma product containing the participant's natural endogenous growth factors and cytokines. PRP has been studied and found to be effective and safe without serious side effects in specialties such as orthopedics and dermatology.

5.1 Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

- *If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*

Once the participant's blood is drawn using the appropriate collection tubes and labeled with participant's unique study identifier and date, it will be transported within 30 minutes to a centrifugation machine located within the same facility (MedStar Lafayette Centre). The participant's blood will be processed using the Arthrex Angel® system (Arthrex, Inc. Naples, Florida) which deposits the PRP into a pre-loaded syringe which will be transported back to the clinic office.

The contents of the PRP syringe will then be injected into the anterior vaginal wall +/- periclitoral tissues per intervention assignment by a trained physician. There will be no storage necessary as PRP does not need to be refrigerated if used on the same day. We will be following a standardized protocol previously established by the MedStar Lafayette Centre orthopedics department where the PRP is utilized within 2 hours of centrifugation.

5.2 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information: N/A

6.0 Procedures Involved*

6.1 Describe and explain the study design.

Single-blind, randomized, sham-controlled trial study design.

6.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

Study activity	Baseline	Intervention (D0)	D0+ 6 weeks	D0+ 3 months?	D0+ 6 months
Informed consent	x				
Eligibility screening	x				
PRP procedure		x			
VAS		x*			
FSFI		x	x	x	x
PGI-I			x	x	x
Adverse Event assessment			x	x	x
Compensation		$50			$50

Visit #1: Screening, Baseline & Enrollment (virtual visit)
This visit may be done virtually or in person by trained research team members. Adult sexually-active natal females interested in participation will view a short power-point orienting them to the research study and offering background about PRP and its proposed benefit for sexual function. Afterwards, a research team member will review the study and informed consent form, answer any questions, and, if they are interested in participating, the coordinator will send an electronic consent via the Interlace platform. After consent is obtained, the subject will be enrolled and the subject will be asked to complete the baseline questionnaires (see appendix).

After confirming eligibility, subjects will be scheduled to attend the in-person procedure visit (visit #2).

Visit #2: Randomization & Intervention (in-person visit)- DAY 0
The subject will then undergo a venipuncture and 40-60 cc of whole blood will be collected. The blood sample will be centrifuged for 15 minutes and spun down according to the PRP kit preparation protocol for the Arthrex Angel system by a trained research team member. On average, 2-4 cc of leukocyte-rich, injectable PRP is produced per 40-60 cc of whole blood. The remaining blood product will be properly disposed of.

Prior to the performance of the injection procedure, the unblinded research staff will complete the randomization in REDCap to obtain the treatment assignment.

After positioning the patient and prepping the vaginal tissues the injections will be performed as follows (see figure):

Anterior vaginal wall injection: The anterior vaginal wall injection of two-thirds PRP isolate volume will be performed in standard fashion for all participants using a a small-gauge needle (28-32 gauge). Two-thirds of the PRP injectate volume obtained will be injected into the distal anterior vaginal wall approximately 3 cm from the urethral meatus. This injection will be superficial and just deep to the vaginal epithelium.

Periclitoral injection: For the peri-clitoral injection, a small-gauge needle (28-32 gauge) will be used. Approximately 1 mL total (or one-third of the obtained PRP isolate volume) of either the PRP or a sham injection will be injected as two small superficial injections of approximately 0.5 mL each, placed near the junction of the clitoris, clitoral hood, and frenulum. If the patient randomizes to sham injection, the needle tip will be inserted under the tissue but no substance will be injected. Given the vascular and densely innervated nature of this region, injections will be performed carefully using a superficial technique with retrograde withdrawing to maximize comfort and minimize risk.

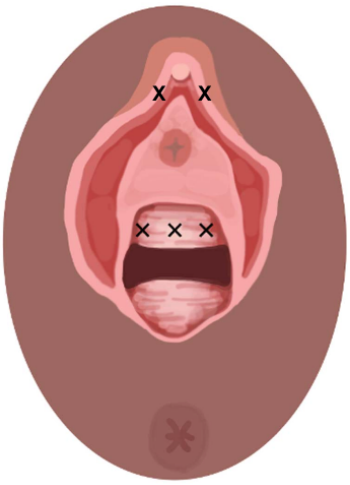


Figure: Injection locations

The patient will complete a VAS questionnaire regarding the procedure and be monitored for 15 minutes following injection. The treatment visit is expected to take approximately 60 minutes.

Participants will receive $50 compensation in the form of a Visa giftcard after this procedural visit.

Visit #3 Follow-up (6 weeks ± 7 days via virtual visit)
The subject will complete the follow-up visit survey including the FSFI questionnaire and the PGI-I questionnaire (see appendix). The subject will be asked about any AEs. This visit will be conducted virtually.

Visit #4 Follow-up (3 months± 7 days via virtual visit)
The subject will complete the follow-up visit survey including the FSFI questionnaire and the PGI-I questionnaire (see appendix). The subject will be asked about any AEs. This visit will be conducted virtually.

Visit #4 Follow-up (6 months ± 14 days via virtual visit)
The subject will complete the follow-up visit survey including the FSFI questionnaire and the PGI-I questionnaire (see appendix). The subject will be asked about any AEs. This visit will be conducted virtually. Participants will receive $50 compensation in the form of a Visa giftcard following completion of this visit.

We anticipate that each virtual follow-up visit will take approximately 10–20 minutes.

6.3 Describe:

- *Procedures performed to lessen the probability or magnitude of risks.*

To mitigate potential side effects, only qualified and trained providers- including physicians and advanced practice providers- will administer PRP or placebo injections according to established guidelines. All clinicians performing these injections must be IRB approved study team members with appropriate training.

- *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*

PRP is a substance derived from one's own blood and is therefore not considered a drug.

- *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*

Source records include the electronic medical record. Study data will be stored on REDCap and/or in an electronic password protected drive accessible only to study team members.

6.4 What data will be collected during the study and how that data will be obtained.

The study will collect subjects' responses to validated sexual health questionnaires, as well as basic demographics at the first visit. Data will be gathered online and securely stored in REDCap.

Outcome Variables

- FSFI (baseline, post-procedure): Assesses domains of female sexual function.
- PGI-I (post-procedure): Rates improvement after treatment on a 7-point Likert scale.
- VAS: Single-item pain scale (1–10); to be completed related to injection.

Demographic Variables

- Age
- BMI
- Race/Ethnicity
- Gravidity/Parity
- Sexual orientation & partner identity
- Sexually active within the last 30 days
- Type and frequency of sexual activity (penetrative, non-penetrative)

6.5 If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.

No further data will be collected after the 6-month study period.

6.6 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures: N/A.

7.0 Data and Specimen Banking*

7.1 If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens. N/A

7.2 List the data to be stored or associated with each specimen. N/A

7.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. N/A

8.0 Sharing of Results with Subjects*

8.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared.

Study results will not specifically be shared with participants. We plan to submit results for presentation at a scientific meeting in abstract form and the manuscript will be submitted to be published in a peer-reviewed journal for dissemination.

9.0 Study Timelines*

9.1 Describe:

- *The duration of an individual subject's participation in the study.*

We estimate each participant will be enrolled for approximately 7 months.

- *The duration anticipated to enroll all study subjects.*

We anticipate enrolling all study subjects will take approximately 12 months, given the sample size of 58 participants.

- *The estimated date for the investigators to complete this study (complete primary analyses)*

We estimate it will be approximately 18 months from enrollment start to completion of primary analysis, reflecting a 12-month enrollment period followed by 6 months of follow-up for the last participant enrolled. Thus, we estimate primary analysis will be completed by approximately February 2028 if enrollment is started August 2026.

	2026				2027				2028	
	PGY5		PGY6				PGY7			
Activity	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
IRB Approval										
Recruitment										
Data Collection										
Data Analysis										
Results Preparation										

10.0 Inclusion and Exclusion Criteria*

10.1 Describe how individuals will be screened for eligibility.

Screening will occur over the phone or in person at MedStar Health clinics by trained research staff.

10.2 Describe the criteria that define who will be included or excluded in your final study sample.

Inclusion criteria:

- Natal adult (18+) females
- Sexually active, with at least one episode of sexual activity (alone or with a partner) in the past month
- English speaking
- Able to complete questionnaires and willing to undergo procedure

Exclusion criteria:

- Pregnancy*, breastfeeding or lactating- excluded via self-responses, participants will sign consent acknowledging that PRP has not been studied in pregnancy
- Active infection or autoimmune condition
- Pelvic radiation/malignancy
- Anticoagulation
- Prior urogenital PRP
- Hx of female genital mutilation
- Presence of urethrovaginal mesh
- Chronic or acute pelvic pain preventing exam, active genital infection

*Individuals who are attempting to conceive, including via in vitro fertilization (IVF) or other fertility treatments, but who are not currently pregnant, are not excluded from study participation. Only confirmed or suspected pregnancy is exclusionary; all participants are counseled that the effects of PRP before or during pregnancy are unknown.

The following special populations will **not** be included:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners

11.0 Vulnerable Populations*

11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare. N/A

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally.

We plan to enroll 58 local subjects.

12.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.). N/A.

13.0 Recruitment Methods

13.1 Describe when, where, and how potential subjects will be recruited.

A member of the research team will reach out to the eligible patients for recruitment and consent. This may be done in person or remotely.

13.2 Describe the source of subjects.

Adult natal females within the MedStar health system and in the DMV area. Recruitment will focus on individuals in the Washington, DC metropolitan area who may meet eligibility criteria for the study.

13.3 Describe the methods that will be used to identify potential subjects.

We plan to recruit participants via MedStar health clinics using flyers and plasma screen advertisements, and local medical spas using IRB-approved recruitment methods and materials. Interested individuals may contact the study team directly or submit their contact information through a secure REDCap database linked through recruitment materials or advertisements.

Recruiting materials will contain a QR code linking to the ClinicalTrials.gov study page and REDCap database.

Participants may additionally be referred by their clinical provider.

We will additionally perform a bioinformatic query in the MedStar electronic medical record to identify patients who may meet study inclusion and exclusion criteria. A one-time patient portal message will be sent to potentially eligible individuals inviting them to participate (see IRB application attachment “Patient Portal Message”). Interested individuals will have the opportunity to provide their contact information through a secure REDCap database.

13.4 Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Recruitment materials will include:

- Printed recruitment flyers for posting in clinics, hospital common areas, and external community locations including medical spas.
- MedStar plasma screen advertisements.
- A patient portal recruitment message distributed through the MedStar electronic medical record to patients identified by their provider.
- ClinicalTrials.gov study listing.

13.5 Describe the amount and timing of any payments to subjects.

Participants will receive up to $100 total compensation for participation as follows:

- $50 after completion of the procedure visit
- $50 after completion of the 6-month follow-up visit

Participants who withdraw from the study prior to completion will receive compensation only for study visits and questionnaires completed up to the time of withdrawal. Compensation is intended to reimburse participants for their time and is not intended to be coercive.

14.0 Withdrawal of Subjects*

14.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Subjects may be withdrawn from the research without their consent if:

- They are found after enrollment to not meet eligibility criteria.
- They develop a medical condition or adverse event that, in the opinion of the investigators, makes continued participation unsafe.
- They fail to comply with study procedures or follow-up requirements. Subjects may also be withdrawn from participation if they are unable to be reached after several attempts to contact.
- The study is terminated by the investigator, sponsor, MHRI, or IRB.

The investigator may also withdraw a participant if continuation in the study is judged not to be in the participant's best interest. If an individual participant is withdrawn from the study, no additional study interventions will be performed. The reason for withdrawal and the participant's status at the time of withdrawal will be documented in the study records..

14.2 Describe any procedures for orderly termination.

If the study is terminated early, subjects who have not yet completed follow-up will be notified. Any participants actively undergoing follow-up will be offered appropriate safety follow-up as determined by the principal investigator.

14.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

Subjects may voluntarily withdraw from the study at any time without penalty or loss of benefits to which they are otherwise entitled. Subjects will be free to withdraw from the study at any point in time for any reason. Subjects electing to withdraw will be considered withdrawn from the study once they have notified the research team of their wish to withdraw. At the time of withdrawal, subjects will be asked to complete final study questionnaires if they are willing to do so and they will be queried regarding their reason for withdrawal. After that point no further data will be collected from the subject. Previously collected data will be retained within the study dataset.

At the time of withdrawal, the study team will document:

- The date and reason for withdrawal, if provided
- Whether continued safety follow-up is needed

Participants who withdraw will not lose compensation already earned for completed study activities.

15.0 Risks to Subjects*

15.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

Participation in this study involves risks related to blood collection, platelet-rich plasma (PRP) preparation, peri-clitoral injections, study questionnaires, and potential loss of confidentiality.

- **Injection Procedure Risks:**
  Subjects may experience pain, discomfort, pressure, burning, or tenderness during or after the injections despite the use of topical anesthetic. Because the peri-clitoral region is highly innervated and vascular, temporary heightened sensitivity or discomfort may occur. Minor bleeding, bruising, swelling, redness, irritation, or localized inflammation may occur at the injection sites. These effects are anticipated to be mild to moderate in severity, temporary, and generally self-limited over several days to weeks.

  There is a small risk of infection associated with needle injections and blood collection. Standard sterile technique will be used to minimize this risk. There is also a small risk of injury to nearby blood vessels, nerves, or

surrounding tissues, which could theoretically result in prolonged pain, altered sensation, numbness, hypersensitivity, or sexual dysfunction. Although these complications are considered unlikely, the duration and reversibility are uncertain if they occur.

- **Risks Related to Blood Draw and PRP:**
  Subjects may experience vasovagal symptoms such as dizziness, nausea, sweating, or fainting related to blood draws or injections. Temporary spotting or vaginal discharge may also occur following the procedure. PRP is an autologous blood product prepared from the participant's own blood, which reduces the risk of allergic reaction or disease transmission.
- **Questionnaire and Psychological Risks:**
  Participants could experience embarrassment, emotional discomfort, anxiety, or psychological distress when answering sensitive questions regarding sexual health, intimacy, or body image.
- **Confidentiality Risks:**
  There is a potential risk of loss of confidentiality regarding sensitive medical and sexual health information collected during the study. Unauthorized disclosure could potentially result in social, emotional, relationship, or economic harms. Multiple safeguards, including using MHRI REDCap electronic databases, password-protected systems within MHRI's secure server for storing all electronic data containing PHI, limited study personnel access, comprehensive HIPAA training for personnel, restricting access to sensitive data to approved research personnel only, and de-identification of research data where feasible, will be used to minimize this risk.
- **Time and Convenience Burden:**
  Participation may require inconvenience related to travel, study visits, questionnaires, blood collection, and follow-up assessments.

Overall, most anticipated risks are expected to be mild, temporary, and reversible. However, because PRP formulations are not standardized and peri-clitoral PRP use for sexual function is investigational, there may be unknown or unforeseeable risks. The effectiveness of the intervention is also unknown.

15.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

Because peri-clitoral injection of platelet-rich plasma (PRP) for the treatment of female sexual dysfunction is investigational, there may be risks that are currently unforeseeable. Potential risks are reviewed above in section 15.1.

15.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

The potential risks of peri-clitoral and vaginal PRP injections to an embryo or fetus are unknown. Although PRP is derived from the participant's own blood product, the effects

of the investigational procedure before or during pregnancy have not been studied. For this reason, pregnant individuals will be excluded from participation.

15.4 If applicable, describe risks to others who are not subjects.

There is a potential indirect risk related to loss of confidentiality of sensitive sexual health information, which could potentially affect personal relationships or partners if private information were inadvertently disclosed. Appropriate safeguards will be used to minimize risks to confidentiality.

16.0 Potential Benefits to Subjects*

16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.

Subjects may or may not experience direct benefit from participation in this study. Potential benefits may include improvement in aspects of sexual function. Because this intervention is investigational, the likelihood, magnitude, and duration of any benefit are unknown and any improvement experienced by participants may be temporary, partial, or absent. It is also possible that participants will experience no clinical benefit from participation.

16.2 Indicate if there is no direct benefit. Do not include benefits to society or others. N/A.

17.0 Data Management* and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analysis.

Randomization:

The subject will be blinded to the treatment allocation, but the injector will be aware. The code will be broken only after the study is complete. At this point all the research team will be made aware of the results. During the study, the blinding may be broken only in emergencies when knowledge of the subject's treatment group is necessary for further subject management. When possible, the Investigator will discuss the emergency with the monitor (the IRB) prior to unblinding. The unblinded research staff will complete the randomization in REDCap to obtain the treatment assignment at the procedure visit.

Sample Size:

The planned sample size is based on a superiority design. The comparison will be made using a two-sided, two-sample t-test based on the difference of the means of baseline/6-week differences of each group, with a Type I error rate (α) of 0.05. The standard deviation of measurements at the first time point is assumed to be 5.1, the standard deviation of measurements at the second time point is assumed to be 5.1, and the

correlation between measurement pairs is assumed to be 0.5. To detect a difference (of differences) of 4.05 (MCID of FSFI, Sarebani et al.) with 80% power, the number of subjects needed will be 26 in Arm A and 26 in Arm B, for a total sample size of 52. Anticipating a 10% dropout rate, 29 subjects will be enrolled in Arm A and 29 in Arm B, for a total enrollment of 58. The sample size was computed using PASS 2024, version 24.0.6.

	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
Dropout Rate	N1	N2	N	N1'	N2'	N'	D1	D2	D
10%	41	41	82	46	46	92	5	5	10
10%	26	26	52	29	29	58	3	3	6
10%	48	48	96	54	54	108	6	6	12
10%	30	30	60	34	34	68	4	4	8
10%	30	30	60	34	34	68	4	4	8
10%	19	19	38	22	22	44	3	3	6
10%	34	34	68	38	38	76	4	4	8
10%	22	22	44	25	25	50	3	3	6

Analysis of data:

Analyses will use two-sided tests at $\alpha=0.05$, with FDR correction (Benjamini-Hochberg) applied to secondary analyses of the primary outcome and to secondary outcomes. Missing data will be handled via complete-case analysis per outcome. Descriptive statistics (means/SDs or medians/IQRs for continuous variables; frequencies/percentages for categorical) will be reported overall and by treatment arm.

Primary outcome (FSFI): the primary analysis compares baseline-to-6-week change between arms using a two-sample t-test, reporting mean change per arm, between-group difference, 95% CI, and p-value. Secondary analyses of FSFI include logistic regression (adjusted for baseline) for two binary endpoints - achieving a 4.05-point clinically meaningful improvement, and exceeding the 26.55 clinically relevant threshold at 6 weeks - each reporting adjusted odds ratios, 95% CI, and p-values. A longitudinal analysis uses linear mixed-effects models (treatment, time, treatment×time, baseline FSFI, random intercept) to compare estimated marginal means between arms at 6 weeks, 3 months, and 6 months.

Secondary outcomes: FSFI subdomains (1-6) use the same mixed-effects modeling approach as the longitudinal FSFI analysis. PGI-I (outcome 7) uses cumulative logit mixed-effects models (treatment, time, treatment×time, random intercept), reporting odds ratios at each time point. VAS pain at injection (outcome 8) is summarized descriptively via means and proportions (VAS ≤ 6) with 95% CIs per arm, testing whether pain is acceptably low. Adverse events (outcome 9) use Poisson regression with robust standard errors (offsetting for follow-up duration if it varies), reporting incidence rate ratios, 95%

CI, and p-values, with the hypothesis of no significant difference in event rates between arms.

17.2 Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

Research records will be accessible only to authorized study team personnel. Electronic study data will be stored in a secure REDCap database and on Medstar protected electronic drives. Paper consent forms and any other research-related paper documents will be stored in locked offices or locked cabinets accessible only to study personnel.

Study data and documents will be retained for the required institutional and regulatory retention period. After the required retention period has ended and study analyses and publications are complete, electronic records will be securely deleted and paper records will be shredded or otherwise destroyed in accordance with institutional policy.

17.3 Describe any procedures that will be used for quality control of collected data. N/A

17.4 Describe how data or specimens will be handled study-wide:

- *What information will be included in that data or associated with the specimens?*
- *Where and how data or specimens will be stored?*
- *How long the data or specimens will be stored?*
- *Who will have access to the data or specimens?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How data or specimens will be transported?*

During the study procedure, a blood specimen will be obtained and processed for preparation of the study treatment. The specimen will exist only for the short interval between blood collection, PRP preparation, and injection. It will be handled only by trained study personnel and will be labelled with the unique study subject ID and procedure date.

Any remaining blood product or unused specimen will be discarded immediately after the procedure in accordance with institutional biohazard waste procedures. No specimens will be stored for future research or future testing. Please see Section 18.2 for details regarding access to study data and procedures for data storage.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

This section is required when research involves more than Minimal Risk to subjects.

18.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.*
- *What data are reviewed, including safety data, untoward events, and efficacy data.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the data.*
- *The frequency or periodicity of review of cumulative data.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that trigger an immediate suspension of the research.*

Because this study involves an investigational peri-clitoral injection procedure, the research team will perform ongoing monitoring of participant safety throughout the study.

Overall expected risks are anticipated to be rare in occurrence given no reported adverse reactions after vaginal PRP injections. Anticipated and known risks will be disclosed to the participants via the informed consent process. All study participants will be closely monitored for adverse events and at 50% enrollment a safety monitor will review all AE and safety data. All study investigators will receive training on the study protocol and AE monitoring.

An adverse event (AE) will be defined as any unfavorable or unintended symptom or sign, temporarily associated with an investigational intervention during the conduct of a clinical trial. Pre-existing diseases or conditions will not be considered AEs unless there is an increase in the frequency or severity, or change in the quality, of the disease or condition. Events that occur in patients treated with placebo will also be considered AEs. AEs will be recorded and serious adverse events will be considered an adverse events that either: (1) results in death, (2) is life threatening, (3) requires inpatient hospitalization, (4) results in permanent or significant disability or incapacity, or (5) is another medically important condition. All serious adverse events will be reported to the MHRI IRB during which time study enrollment will be stopped and the safety monitor will conduct a review to assess safety of study continuation.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

We will make all effort to have participants interact with consistent study team personnel throughout their participation in the trial. Research-related visits will be conducted with the research team member in a private setting and settings of the participant's choice if conducted via telephone and in a private office setting if in person.

19.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Participants will be informed during the consent process that participation is entirely voluntary and that they may withdraw from the study at any time without penalty or effect on their clinical care. The study team will explain the study procedures in detail before participation, including that questionnaires will ask about sexual function, sexual distress, and related sensitive topics.

Study personnel will use respectful, nonjudgmental, and clinically appropriate language when discussing sensitive information. Participants will be given time to ask questions before agreeing to participate and throughout the study. Only trained study personnel will be involved in collecting sensitive information or performing study-related procedures.

19.3 Indicate how the research team is permitted to access any sources of information about the subjects.

The research team will have access to the REDCap database. The research team will be able to access the patient's electronic medical record and any data generated from this study only to the extent needed to complete the study procedures.

A HIPAA waiver is requested to screen patient charts for those meeting inclusion criteria on the outpatient clinic schedules. Subjects will be enrolled and consented before any additional information is collected. Members of the research team will collect data from chart review both before and after the study visit

20.0 Compensation for Research-Related Injury

20.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

There is no available compensation for research-related injury, which is not anticipated.

20.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury. N/A

21.0 Economic Burden to Subjects

21.1 Describe any costs that subjects may be responsible for because of participation in the research.

There is only one required in-person appointment and we will cover the cost of parking for any in person study visits. Otherwise, there is no anticipated additional cost for participation.

22.0 Consent Process

22.1 Indicate whether you will you be obtaining consent, and if so describe:

- *Where will the consent process take place*
- *Any waiting period available between informing the prospective subject and obtaining the consent.*
- *Any process to ensure ongoing consent.*
- *Whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, describe:*
  - *The role of the individuals listed in the application as being involved in the consent process.*
  - *The time that will be devoted to the consent discussion.*
  - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
  - *Steps that will be taken to ensure the subjects' understanding.*

Potential subjects will initially be screened during a virtual visit. Written or electronic informed consent will be obtained before any study treatment or intervention is performed.

During both the verbal discussion and written/electronic informed consent process, an authorized study team member will explain the study purpose, procedures, risks, benefits, alternatives, and participant responsibilities using clear and understandable language. Participants will be informed that participation is voluntary, that they may decline to participate or withdraw at any time, and that their decision will not affect their current or future clinical care. The study team member obtaining consent will assess the participant's capacity to understand the information and provide informed consent. All consent discussions will use objective, non-coercive language, and only authorized study team members will obtain consent.

Non-English Speaking Subjects N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception) N/A

Subjects who are not yet adults (infants, children, teenagers) N/A

Cognitively Impaired Adults N/A

Adults Unable to Consent N/A

23.0 Process to Document Consent in Writing

23.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be documented in writing.

A written consent document created from MHRI Consent Document HRP-502 will be used to document consent in writing (refer to ICF document). See section 17.2 and 22.1.

23.2 If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. N/A

23.3 (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script.) To be attached.

24.0 HIPAA Authorization

Request for a Waiver of HIPAA Authorization: regardless of IRB review category, for a chart review study involving Protected Health Information (PHI) a Waiver of HIPAA Authorization for the use or disclosure of PHI needs to be requested and obtained. The following elements from 45 CFR 164.512 (i) (1) (i) must be met for the IRB to waive the requirement:

24.1 A waiver of HIPAA authorization is being requested solely for the purposes of screening patient charts and contacting patients for potential enrollment in this research study. All subsequent research activities will be performed with patient consent.

- The use or disclosure of protected health information during the screening and recruitment process of the research involves no more than minimal risk to privacy of individuals.
- As the HIPAA waiver is requested solely for the screening and recruitment process. A screening log will be maintained with the same confidentiality and security as the study database to track which patients have been contacted,

consented, or declined participation. All patient information for this study will be maintained in a confidential database on the MedStar OneDrive, accessible only to members of the research team listed on the IRB application.

- Identifiers will be destroyed at the earliest opportunity once all research activities have been completed. No identifiers will be collected solely from the screening process for which a HIPAA waiver is requested.
- This study involves reviewing and collecting data on patient medical and surgical history. Confidentiality risk is minimized through using standard HIPAA provision and data security. All MedStar HIPAA policies will be followed. No information will be collected in a research database unless patients enroll in the study and sign a consent form. Study documents are saved on password protected drives, no identifiable data will be transferred from the covered entity and access is restricted to personnel listed on the IRB-approved study.
- This research could not practicably be conducted without access to and use of the protected health information as it would require a member of the study research team to be present in all our clinical sites during all provider clinics and at our hospitals on day of surgery for enrollment and consent which is not logistically feasible.

25.0 Setting

25.1 Describe the sites or locations where your research team will conduct the research.

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where research procedures will be performed.*
- *Describe the composition and involvement of any community advisory board.*
- *For research conducted outside of the organization and its affiliates describe:*
  - *Site-specific regulations or customs affecting the research for research outside the organization.*
  - *Local scientific and ethical review structure outside the organization.*

Please see Section 14.0 for recruitment processes and locations, and please see the Appendix for the patient-facing recruitment materials.

Study team members will conduct any virtual visits from quiet, private locations to ensure confidentiality and prevent inadvertent disclosure of HIPAA-protected information. In person visits will be conducted at MedStar Health outpatient clinics or research offices. All questionnaires will be completed electronically on participants' personal devices, on paper, or using a clinic-provided tablet or computer.

26.0 Resources Available

26.1 Describe the resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
- *Describe the time that you will devote to conducting and completing the research.*
- *Describe your facilities.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

Given the total planned sample size of 58 subjects, with recruitment throughout MedStar and the Washington, D.C. community, we do not anticipate difficulty recruiting participants over the 12-month enrollment period.

Injection procedure visits will take place at MedStar Health at Lafayette Centre, located at 1131 21st St NW, Washington, DC 20036. This is a multidisciplinary outpatient clinic. All study materials, including the PRP centrifuge, are available on site. Available facilities include private clinic rooms, private procedure rooms, and clinical offices. During the procedure, standard clinical office procedural room sterility and safety measures will be followed, and the necessary equipment will be available to meet the standard of care for the clinical situation.

As with any clinical encounter or procedure performed at MedStar, medical and psychological resources will be available to subjects should they require them. Prior to study initiation, all study team members will have obtained IRB approval and will review the study protocol to ensure they understand their roles as study personnel and the study procedures.

27.0 Multi-Site Research* N/A

Appendix 28.1
FSFI Questionnaire

Female Sexual Function Index (FSFI) ©

Subject Identifier _____ Date _____

INSTRUCTIONS: These questions ask about your sexual feelings and responses during the past 4 weeks. Please answer the following questions as honestly and clearly as possible. Your responses will be kept completely confidential. In answering these questions the following definitions apply:

Sexual activity can include caressing, foreplay, masturbation and vaginal intercourse.

Sexual intercourse is defined as penile penetration (entry) of the vagina.

Sexual stimulation includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

CHECK ONLY ONE BOX PER QUESTION.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

1. Over the past 4 weeks, how **often** did you feel sexual desire or interest?

   ☐ Almost always or always
   ☐ Most times (more than half the time)
   ☐ Sometimes (about half the time)
   ☐ A few times (less than half the time)
   ☐ Almost never or never

2. Over the past 4 weeks, how would you rate your **level** (degree) of sexual desire or interest?

   ☐ Very high
   ☐ High
   ☐ Moderate
   ☐ Low
   ☐ Very low or none at all

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.

3. Over the past 4 weeks, how **often** did you feel sexually aroused ("turned on") during sexual activity or intercourse?

   - ☐ No sexual activity
   - ☐ Almost always or always
   - ☐ Most times (more than half the time)
   - ☐ Sometimes (about half the time)
   - ☐ A few times (less than half the time)
   - ☐ Almost never or never

4. Over the past 4 weeks, how would you rate your **level** of sexual arousal ("turn on") during sexual activity or intercourse?

   - ☐ No sexual activity
   - ☐ Very high
   - ☐ High
   - ☐ Moderate
   - ☐ Low
   - ☐ Very low or none at all

5. Over the past 4 weeks, how **confident** were you about becoming sexually aroused during sexual activity or intercourse?

   - ☐ No sexual activity
   - ☐ Very high confidence
   - ☐ High confidence
   - ☐ Moderate confidence
   - ☐ Low confidence
   - ☐ Very low or no confidence

6. Over the past 4 weeks, how **often** have you been satisfied with your arousal (excitement) during sexual activity or intercourse?

   - ☐ No sexual activity
   - ☐ Almost always or always
   - ☐ Most times (more than half the time)
   - ☐ Sometimes (about half the time)
   - ☐ A few times (less than half the time)
   - ☐ Almost never or never

7. Over the past 4 weeks, how **often** did you become lubricated ("wet") during sexual activity or intercourse?

   - ☐ No sexual activity
   - ☐ Almost always or always
   - ☐ Most times (more than half the time)
   - ☐ Sometimes (about half the time)
   - ☐ A few times (less than half the time)
   - ☐ Almost never or never

8. Over the past 4 weeks, how **difficult** was it to become lubricated ("wet") during sexual activity or intercourse?

   - ☐ No sexual activity
   - ☐ Extremely difficult or impossible
   - ☐ Very difficult
   - ☐ Difficult
   - ☐ Slightly difficult
   - ☐ Not difficult

9. Over the past 4 weeks, how often did you **maintain** your lubrication ("wetness") until completion of sexual activity or intercourse?

   - ☐ No sexual activity
   - ☐ Almost always or always
   - ☐ Most times (more than half the time)
   - ☐ Sometimes (about half the time)
   - ☐ A few times (less than half the time)
   - ☐ Almost never or never

10. Over the past 4 weeks, how **difficult** was it to maintain your lubrication ("wetness") until completion of sexual activity or intercourse?

    - ☐ No sexual activity
    - ☐ Extremely difficult or impossible
    - ☐ Very difficult
    - ☐ Difficult
    - ☐ Slightly difficult
    - ☐ Not difficult

11. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **often** did you reach orgasm (climax)?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

12. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **difficult** was it for you to reach orgasm (climax)?

- ☐ No sexual activity
- ☐ Extremely difficult or impossible
- ☐ Very difficult
- ☐ Difficult
- ☐ Slightly difficult
- ☐ Not difficult

13. Over the past 4 weeks, how **satisfied** were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

14. Over the past 4 weeks, how **satisfied** have you been with the amount of emotional closeness during sexual activity between you and your partner?

- ☐ No sexual activity
- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

15. Over the past 4 weeks, how **satisfied** have you been with your sexual relationship with your partner?

- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

16. Over the past 4 weeks, how **satisfied** have you been with your overall sexual life?

- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

17. Over the past 4 weeks, how **often** did you experience discomfort or pain during vaginal penetration?

- ☐ Did not attempt intercourse
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

18. Over the past 4 weeks, how **often** did you experience discomfort or pain following vaginal penetration?

- ☐ Did not attempt intercourse
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

19. Over the past 4 weeks, how would you rate your **level** (degree) of discomfort or pain during or following vaginal penetration?

- ☐ Did not attempt intercourse
- ☐ Very high
- ☐ High
- ☐ Moderate
- ☐ Low
- ☐ Very low or none at all

Thank you for completing this questionnaire

Appendix 28.2 PGI-I Questionnaire

Patient Global Impression of Improvement (PGI-I)

INSTRUCTIONS: Check the number that best describes how you feel after receiving the injections.

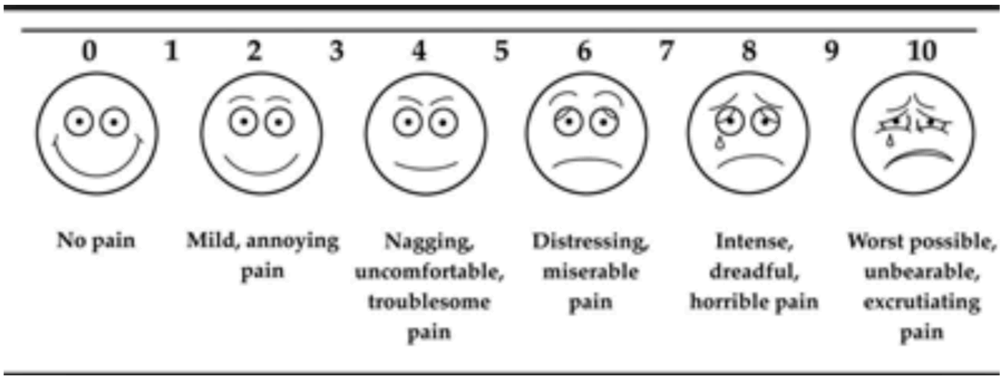
How is your sexual function now compared to before you received your treatment?

- ☐ Very much better (0)
- ☐ Much better (1)
- ☐ A little better (2)
- ☐ No change (3)
- ☐ A little worse (4)
- ☐ Much worse (5)
- ☐ Very much worse (6)

Appendix 28.3 Visual Analogue Scale (after injection)

Visual Analog Scale (VAS)

Instructions: Please rate your pain for the injection process



Appendix 28.4 Patient Intake Form

Study ID: _____
Date Completed: _____
Completed By: _____

Preferred Name

Preferred Pronouns

Phone Number

Email Address

Preferred Method of Contact

- ☐ Phone
- ☐ Email
- ☐ Patient Portal
- ☐ Text Message

Is it okay to leave a voicemail regarding the study?

- ☐ Yes
- ☐ No

1. Age

- Date of Birth: ____ / ____ / _____
- Current Age: _____ years

2. Sex Assigned at Birth

- ☐ Female
- ☐ Male
- ☐ Intersex
- ☐ Prefer not to answer

3. Gender Identity

- ☐ Woman
- ☐ Man
- ☐ Non-binary
- ☐ Genderqueer / Gender non-conforming
- ☐ Prefer to self-describe: _____
- ☐ Prefer not to answer

4. Sexual Orientation

- ☐ Heterosexual / Straight
- ☐ Lesbian
- ☐ Bisexual
- ☐ Pansexual
- ☐ Queer
- ☐ Asexual
- ☐ Prefer to self-describe: _____
- ☐ Prefer not to answer

5. Race (Select all that apply)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Other: _____
- ☐ Prefer not to answer

6. Ethnicity

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Prefer not to answer

7. Relationship Status

- ☐ Single
- ☐ Married
- ☐ Partnered
- ☐ Divorced

- ☐ Separated
- ☐ Widowed
- ☐ Prefer not to answer

8. Employment Status

- ☐ Full-time
- ☐ Part-time
- ☐ Student
- ☐ Unemployed
- ☐ Retired
- ☐ Other: _____

9. Highest Level of Education Completed

- ☐ Less than high school
- ☐ High school diploma or GED
- ☐ Some college
- ☐ Associate degree
- ☐ Bachelor's degree
- ☐ Graduate or professional degree
- ☐ Prefer not to answer

10. Are you currently sexually active? (defined as at least one episode of sexual activity, alone or with a partner, in the last 30 days)

- ☐ Yes
- ☐ No

11. What genders are your sexual partners? (Select all that apply)

- ☐ Man
- ☐ Woman
- ☐ Non-binary
- ☐ Prefer not to answer

12. Have you experienced concerns related to sexual function?

- ☐ Yes
- ☐ No

13. If yes to #12, which symptoms are most bothersome? (Select all that apply)

- ☐ Low sexual desire
- ☐ Difficulty with arousal
- ☐ Difficulty achieving orgasm
- ☐ Decreased genital sensation
- ☐ Pain with sexual activity
- ☐ Vaginal dryness
- ☐ Sexual distress
- ☐ Other: _____

14. How long have these symptoms been present?

- ☐ Less than 6 months
- ☐ 6–12 months
- ☐ 1–3 years
- ☐ More than 3 years

15. Are you currently pregnant?

- ☐ Yes
- ☐ No
- ☐ Unsure

16. Are you currently breastfeeding?

- ☐ Yes
- ☐ No

17. Have you gone through menopause?

- ☐ Yes
- ☐ No
- ☐ Unsure

18. Do you have any of the following medical conditions? (Select all that apply)

- ☐ Bleeding disorder

- ☐ Platelet disorder
- ☐ Active pelvic infection
- ☐ Active sexually transmitted infection
- ☐ Chronic pelvic pain condition
- ☐ Neurologic disorder affecting sexual function
- ☐ Autoimmune disease
- ☐ Cancer currently undergoing treatment
- ☐ None of the above
- ☐ Other significant medical condition: _____

19. Have you had any prior procedures or surgeries involving the vulva, clitoris, or vagina?

- ☐ Yes
- ☐ No

If yes, please describe:

20. Have you previously received PRP injections or other regenerative therapies for sexual function?

- ☐ Yes
- ☐ No

If yes, please describe:

21. Are you currently taking any of the following medications? (Select all that apply)

- ☐ Anticoagulants / blood thinners
- ☐ Chronic opioid medications
- ☐ Immunosuppressive medications
- ☐ Hormone replacement therapy
- ☐ Testosterone therapy
- ☐ None of the above
- ☐ Other medications relevant to sexual function (ie Addyi, etc):
  _____

22. Do you have any allergies to topical anesthetics such as benzocaine, lidocaine, or tetracaine?

- ☐ Yes

- ☐ No
- ☐ Unsure

23. Have you had any recent genital, vaginal, or urinary infections within the past 30 days?

- ☐ Yes
- ☐ No

24. Do you currently have open sores, lesions, or skin irritation in the genital region?

- ☐ Yes
- ☐ No

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