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Title: Investigational Proposal for Preputial Relocation and Maintenance (PRM) as a Non-Surgical Alternative to Infant Circumcision

1. Objective

To evaluate the safety, efficacy, and anatomical viability of Preputial Relocation and Maintenance (PRM) as a non-surgical, tissue-sparing alternative to routine infant male circumcision. The primary clinical goal is to reduce pediatric yeast infections and related morbidities while accommodating populations seeking to avoid surgical modification for cultural or religious reasons.

2. Background and Rationale

Traditional circumcision involves the surgical excision of healthy preputial tissue, which inevitably results in surgical scarring and permanently alters the patient's anatomy. The proposed PRM procedure utilizes the natural elasticity and physiological characteristics of the penile epidermis. The skin in this region is loose and lacks rigid connective tissue anchoring it to the base of the penile shaft, allowing for significant mechanical manipulation and relocation without excision.

3. Proposed Methodology

The PRM procedure involves the strategic repositioning of the foreskin to expose the glans penis without tissue removal permanently:

- **Initial Retraction:** The prepuce is manually retracted down the penile shaft to the base of the penis, fully exposing the glans.
- **Tissue Relocation:** The excess preputial tissue is further drawn downward over the scrotum, anchoring the skin at the perineum.
- **Maintenance Phase:** The relocated tissue is maintained in this targeted perineal position for a continuous period of 8 weeks (2 months).
- **Physiological Adaptation:** This sustained positioning establishes a state of controlled paraphimosis. After the 8-week maintenance phase, the body anatomically adjusts to the new tissue distribution. The skin naturally remains positioned behind the testicles, keeping the glans exposed.

4. Target Population & Benefits

- **Pediatric Patients:** Male infants at risk for recurrent candidiasis or other foreskin-related infections.
- **Cultural/Religious Preservation:** Provides a functional alternative for demographic groups (such as Hebrew and Judaic populations) who wish to maintain an unmodified anatomical state by avoiding surgical amputation of tissue.
- **Wound Healing:** Eliminates the surgical wound, bleeding risks, and subsequent scarring associated with traditional circumcision.

5. Request for Review

This document serves as a preliminary outline for FDA review to determine the classification and necessary clinical trial phases required to test the PRM methodology. Approval is sought to initiate controlled, monitored studies to standardize the 8-week maintenance protocol and evaluate long-term anatomical adaptation.

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