Subject ID: ___ ___ ___ ___ ___ ___ ___ Staff Initials: ___ ___ ___

The eligibility form may be completed over multiple visits. Informed consent must be obtained before completing this form and this form must be complete before randomization.

CONSENT STATUS

Date of original consent: | | | | | | | | | |
Day Month Year

Consented to Version 1. ☐ Y ☐ N
Consented to Version 2. ☐ Y ☐ N
Consented to Version 3. ☐ Y ☐ N

INCLUSION CRITERIA (To be eligible, all answers MUST be YES)

1. Non-pregnant adult female at least 21 years old, with no plans to become pregnant during the course of the trial and if of child-bearing potential, with a negative pregnancy test, and if sexually active, must be using medically acceptable contraception. ☐ Y ☐ N
2. ≥ 6 urge urinary incontinence episodes on a 3-day baseline bladder diary, with these urge incontinence episodes representing greater than 50% of the total incontinent episodes recorded. ☐ Y ☐ N
3. Willing and able to complete all study related items and interviews. ☐ Y ☐ N
4. Refractory urinary urge incontinence: defined as. ☐ Y ☐ N
   a. Persistent symptoms despite at least one or more conservative treatments (e.g. supervised behavioral therapy, supervised physical therapy); and
   b. Persistent symptoms despite the use of a minimum of two anticholinergics, or unable to tolerate medication due to side effects, or has a contraindication to taking anticholinergic medication.
5. Currently not on an anticholinergic or antimuscarinic medication (e.g. oxybutynin, tolterodine, and/or fesoterodine) or be willing to stop medication for 3 weeks prior to completing baseline bladder diary and expected to remain off medications through duration of study. ☐ Y ☐ N
6. Demonstrates ability (or have caregiver demonstrate ability) to perform clean intermittent self-catheterization. ☐ Y ☐ N
7. Grossly neurologically normal on exam and no gross systemic neurologic conditions believed to affect urinary function. ☐ Y ☐ N
8. Urodynamic assessment within the previous 18 months prior to <u>enrollment</u> <u>or done after enrollment</u> prior to randomization. ☐ Y ☐ N

EXCLUSION CRITERIA (To be eligible, all answers MUST be NO)

1. Neurologic diseases such as multiple sclerosis, Parkinson Disease, CVA within 6 months prior to enrollment, myasthenia gravis, Charcot-Marie-Tooth disease, clinically significant peripheral neuropathy and complete spinal cord injury. ☐ Y ☐ N
2. Untreated urinary tract infection (UTI) . ☐ Y ☐ N
3. Any prior use of either study therapy for treatment of urinary urge incontinence (Botox or InterStim) . ☐ Y ☐ N
4. Current participation in any other conflicting interventional research study. ☐ Y ☐ N
5. PVR >150 ml on 2 occasions within 6 months prior to enrollment (If the PVR value was obtained by ultrasound and was ≥150 ml, the PVR will be confirmed by catheterization which will be the gold standard). ☐ Y ☐ N
6. Subjects with knowledge of planned MRIs or diathermy that conflict with Medtronic guidelines (See MOP) ☐ Y ☐ N
7. Current or prior bladder malignancy . ☐ Y ☐ N

Subject ID: ___ ___ ___ ___ ___ ___ ___ Staff Initials: ___ ___ ___

8. Surgically altered detrusor muscle, such as augmentation cystoplasty .. ☐ Y ☐ N
9. Subjects taking aminoglycosides .. ☐ Y ☐ N
10. Currently pregnant or lactating .. ☐ Y ☐ N
11. Subjects who are on ambulatory anticoagulant therapy, including aspirin, who are unable to discontinue treatment for 24 hours prior to bladder injection and staged InterStim® procedure .. ☐ Y ☐ N
12. Serum creatinine level greater than twice the upper limit of normal within the previous year prior to enrollment .. ☐ Y ☐ N
13. Surgical treatment for stress incontinence (sling, Burch or urethral injection) or pelvic organ prolapse recommended or planned at enrollment by study investigator(s) .. ☐ Y ☐ N
14. Prior stress incontinence or prolapse surgery within the last 6 months prior to enrollment .. ☐ Y ☐ N
15. Allergy to lidocaine or bupivacaine .. ☐ Y ☐ N
16. Prior pelvic radiation .. ☐ Y ☐ N
17. Uninvestigated hematuria .. ☐ Y ☐ N
18. Greater than or equal to Stage III vaginal prolapse .. ☐ Y ☐ N
19. Known allergy to Botox A® .. ☐ Y ☐ N
20. Use of a vaginal pessary.. ☐ Y ☐ N

ELIGIBILITY STATUS

Met all eligibility criteria? ☐ Y ☐ N

Date of end of Baseline period: ___ ___ ___ ___ ___ ___ ___ ___
Day Month Year

Opt In/Opt Out Consent

Did subject provide consent for biomarker sample collection? ☐ Y ☐ N

If yes, Date ___ ___ ___ ___ ___ ___ ___ ___
Day Month Year

Did subject provide consent for DNA sample collection? ☐ Y ☐ N

If yes, Date ___ ___ ___ ___ ___ ___ ___ ___
Day Month Year

Did subject provide consent for RUM Supplemental Study? ☐ Y ☐ N

If yes, Date ___ ___ ___ ___ ___ ___ ___ ___
Day Month Year

The following is not to be keyed in the DMS.

Date baseline QOL completed: ___ ___ ___ ___ ___ ___ ___ ___
Day Month Year