## WHAT HAPPENS TO THE INFORMATION COLLECTED?

All research information will be treated confidentially by assigning a number (and not your name) to your study forms.

## HOW LONG WILL I PARTICIPATE?

12 months after treatment starts.

## WILL I BE COMPENSATED?

You will be compensated up to $425 for your participation. All clinic visits for both mirabegron/vibegron and Botox A® are considered normal clinical care and go through your health insurance.

## IF YOU WOULD LIKE MORE INFORMATION ABOUT THE STUDY, PLEASE CALL OR EMAIL:


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## PARTICIPATING UAB PROVIDERS:

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**UROGYNECOLOGY & RECONSTRUCTIVE PELVIC SURGERY**

UAB MEDICINE
The University of Alabama at Birmingham

uabmedicine.org/women

# BEST STUDY

## THERAPY FOR URGENCY URINARY INCONTINENCE

### Watch a short video about the study by scanning below QR code.

1.Open your Camera App
2.Aim your camera at the QR code and make sure it is in focus
3.Tap on the pop-up text that appears
4.You will be brought to the QR code link/information

## WHAT IS URGENCY URINARY INCONTINENCE (UUI)?

Urgency urinary incontinence (UUI) is a sudden, strong urge to urinate that is hard to stop. Women with this type of incontinence may leak urine on the way to the bathroom. Some also have urinary frequency complaints and nighttime urinary problems. It is a common condition that can have a negative effect on a woman's quality of life.

## WHAT ARE THE TREATMENT OPTIONS FOR UUI?

- Behavioral therapy
- Medications
- Onabotulinumtoxin A injection (Botox A®)
- Nerve stimulation

## WHAT IS THIS TRIAL ABOUT?

This study compares mirabegron/vibegron (an oral medication) to Botox A® (an injected medication). Both treatments have been shown to help UUI, but they have not yet been directly compared to each other to see which treatment may be better depending on the individual patient. That is the goal of this study.

- Mirabegron or vibegron:
  - FDA-approved treatment
  - Prescription medication taken by mouth once a day
  - Reduces UUI by relaxing the bladder muscle

- Onabotulinumtoxin A (Botox A®):
  - FDA-approved treatment
  - Injected into the bladder in an office setting
  - Reduces UUI by decreasing bladder contractions

## HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

432 women across 5 sites in the United States will be asked to participate.

About 84 women will be patients from the UAB Women & Infants Center and the communities it serves.

## REQUIREMENTS:

- You must be at least 18 years old and have UUI.
- You do not plan to become pregnant during the trial (12-month duration).
- You have tried anticholinergic medication in the past without improvement.

**You cannot participate if you:**

- Are unable to take medication by mouth or cannot take Botox A® injections
- Previously used mirabegron/vibegron or Botox A®
- Have blood in your urine that has not been evaluated
- Have a history of bladder cancer
- Have received radiation therapy to your pelvis
- Have vaginal prolapse (bulge)