CONSENT FORM FOR RESEARCH

Study title: Using Mirabegron to Increase Blood Pressure in Patients with Postural Orthostatic Tachycardia Syndrome

Study support provided by: American Heart Association

Cedars-Sinai Principal Investigator: Peng-Sheng Chen, MD

Cedars-Sinai study contact phone number: 310-967-3854

Cedars-Sinai after-hours emergency contact (24 hours): Electrophysiologist On-Call, 310-248-6679

To help guide your review of this form, the main sections include:

1. Key Information

Thank you for considering research participation. Research helps make medical and scientific advancements possible. In this form, we are asking for your consent to take part in this research study. Taking part in this research study is voluntary.

This section provides key information about the study. Please take your time to read this entire form. Also, please ask questions before deciding whether to take part in this research study. You are welcome to talk with family, friends and other healthcare providers before you decide.

- **Purpose:** The purpose of this study is to test the hypothesis that mirabegron increases systolic blood pressure (BP), prevents syncope (fainting)/pre-syncope, and improves the quality of life (QOL) and overactive bladder (OAB) symptoms in patients with *postural orthostatic tachycardia syndrome (POTS)* who have a documented history of hypotension inadequately responsive to conventional treatments. This is a dose-ranging study. Section 2 includes more details.

- **Duration:** Taking part in this study will last about 14 weeks.

- **Procedures:** The main things that will happen in this study are taking either a 25 or 50 mg once-daily dose of mirabegron orally for 8 weeks. Additionally, we will perform 24-hr ambulatory blood pressure monitoring (ABPM), and ambulatory skin sympathetic nerve activity (SKNA) recording using a Bittium Faros electrocardiogram (ECG) monitor, assess the number of syncope and pre-syncope episodes and determine the symptoms using validated questionnaires. Section 4 includes more details.

- **Benefits:** The possible benefits of taking part in this study are as follows: (1) Increase in systolic blood pressure, (2) prevent dizziness and syncope (passing out from low blood pressure) and (3) improve the quality of life (QOL) and overactive bladder (OAB) symptoms. Section 3 includes more details.

- **Risks:** All research studies involve some risk. Risks or discomforts from this study may be drug intolerance, at which point participation would terminate. Section 6 includes more details.
    - If you experience side effects or have problems during the study, contact the study team using the contact information on the first page of this consent form.

- **Alternatives:** You can choose not to be in the study. There may be other choices for you. These are described in Section 9 of this form.

- **New Information:** During the study, we may find out new information about this study. We will tell you about any important changes or new findings that may impact your decision to continue taking part in the study.

2. Purpose of the Study

We are doing this study to examine if mirabegron increases systolic blood pressure (BP), prevents syncope(fainting)/pre-syncope, and improves the quality of life (QOL) and overactive bladder (OAB) symptoms in patients with postural orthostatic tachycardia syndrome (POTS).

You are being asked to participate in this research study because you have POTS and a history of hypotension that has not been successfully treated with medications. This means you may feel syncope or pre-syncope. Your doctor may have tried the standard medications used for POTS that have not helped to control blood pressure. Scientists research to answer important questions, which might help change or improve how we do things in the future.

The U.S. Food and Drug Administration (FDA) approved the drug or device for treating OAB in adult patients. Mirabegron is in a class of medications called beta-3 adrenergic agonists. It works by relaxing the bladder muscles to prevent urgent, frequent, or uncontrolled urination. However, in this study, we are using it differently from what was approved by the FDA. Mirabegron can also be used to increase blood pressure. Others have speculated that mirabegron may be useful in treating patients with orthostatic hypotension (low blood pressure) and dysautonomia (a disorder of autonomic nervous system (ANS) function. The ANS is charge of involuntary functions—things that happen without thinking—like breathing. Dysautonomia usually involves failure of the sympathetic (alert) and parasympathetic (relaxed) parts of the ANS), none provided evidence to support that hypothesis. Therefore, this study is a new approach to managing patients with recurrent syncope (fainting).

The study will include up to 20 people total.

3. Main Study Procedures

This section talks about what will happen in this study. When you read this section, also read the table of procedures. The table is given with this consent form.

The table of procedures shows:

- When study procedures will occur,
- Whether they will be covered by the study or billed to you and/or your insurance, and
- Which study procedures are research-related and which are standard of care (routine).

Research-related procedures are procedures done only for the research study. They would not be performed for your routine care outside of the study. **Standard of care (routine) procedures** are routine care generally given to people with your condition. They would be performed even if you did not take part in this study. The researchers will schedule the visits and procedures at the listed timepoints. Any hospitalizations during the study period will be treated as standard of care.

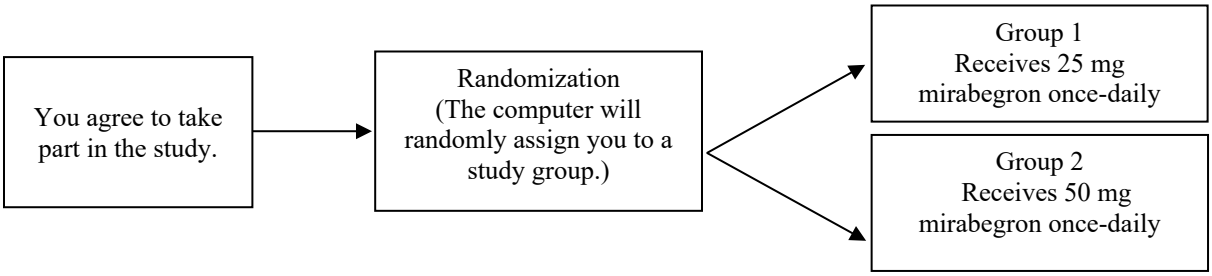
Section 6 describes the common medical procedures that will be done or repeated only because you are in this research study.

Description of main research procedures:

This study has 2 study groups:
- Group 1- will receive 25 mg/day of mirabegron.
- Group 2- will receive 50 mg/day of mirabegron.

This is a randomized research study. Here's a breakdown of what these words mean:
- **Randomized**: This means that you will be put in a study group by chance (like flipping a coin). You will be randomly put in one of the above study groups. You will have a equal chance of being placed in any one of the groups described above. A computer will randomly put you in a study group. We do this because no one knows if the results in one study group will be different than the others. The results could be better, the same or worse than the results in other groups. Once you are put in one group, you cannot switch to another group. You and your doctor cannot choose the group you are in.

You can review the chart below to see what will happen during the study.



Baseline Visit

This visit will take place at the cardiology clinic and it may take up to 2 hours.

During this visit, you will do the following study-related procedures:

- Sign the informed consent form
- Ambulatory SKNA recording – a small heart rhythm monitoring patch that records all heartbeats and determines skin sympathetic nerve activity for 1-7 days.
- 24-hour ambulatory blood pressure monitoring (may not be necessary if already completed as Standard of Care within 6 months prior to Baseline Visit)
- 12-lead ECG
- Active standing test (if tolerated)
- Complete the following questionnaires: EQ-5D-5L, DASI, SAQ, MAP, FSFI (female participants only), OAB-q SF, and PROMIS SF Fatigue 8a
- Receive drug

You will take 8-weeks of the study drug, mirabegron. Despite only needing an 8-week supply for the study, you will be given a 12-week supply of mirabegron to accommodate study visit flexibility. The study team will communicate with you at around 4 weeks to ask how you are

doing and if you are having any problems, side effects, or problems remembering to take the medication. We will ask you for your preferred method of communication - telephone call or email.

4 Week Follow-Up Visit

This visit will take place virtually using your preferred contact method (phone, email, or teleconference) and may last up to 1 hour.

- Assess for adverse events

8 Week Follow-Up Visit

This visit will occur at the cardiology clinic and may last up to 2 hours.

- Ambulatory SKNA recording – a small heart rhythm monitoring patch that records all heartbeats and determines skin sympathetic nerve activity for 1-7 days.
- 24-hour ambulatory blood pressure monitoring
- 12-lead ECG
- Active standing test (if tolerated)
- Complete the following questionnaires: EQ-5D-5L, DASI, SAQ, MAP, FSFI (female participants only), OAB-q SF, and PROMIS SF Fatigue 8a
- Assess for adverse events
- Option to discontinue mirabegron use. You may opt to continue the drug as part of your routine care, however the study will not administer more and is not responsible for this.

12 Week Follow-Up Visit

This visit will take place virtually using your preferred contact method (phone, email, or teleconference) and may last up to 1 hour.

- Assess for adverse events

All procedures, labs, and test performed are considered experimental and are being done for research purposes.

How long will you be in the study?
We think you will be in this study for/until about 14 weeks. The total time includes 4 study visits. Two of these visits will be virtual and two will be in-clinic at Cedars-Sinai Medical Center.

4. Possible Benefits From Taking Part in the Study

Being in this research study may or may not have direct medical benefit to you. The possible benefits of taking part in the research study are (1) Increase in systolic blood pressure, (2) prevent dizziness and syncope (passing out) and (3) improve the quality of life (QOL) and

overactive bladder (OAB) symptoms. However, no benefit is guaranteed. It is possible that your condition may stay the same or even get worse.

We hope the information learned from this research study will help to increase the scope of knowledge and accessibility of OAB medications for the purpose of controlling blood pressure in patients with POTS.

5. Possible Risks and Discomforts of the Main Research Procedures

This section talks about the possible risks and discomforts of the main study procedures.

Risks of common medical procedures being done for research purposes are described below in Section 6. Side effects and risks of standard of care procedures are not described in this consent form.

The study medication may interact with other medications, so consult with our study PI before starting any new medications and diet supplements.

Unknown Risks
There may be other risks that we cannot predict. Many complications are minor and do not last long. However, in some cases, they can be serious, long-lasting, permanent and/or fatal.]

Risks of Mirabegron

Likely (*Out of 100 people, 20 to 100 people may have this happen.)*

- Mirabegron (Myrbetriq) may be associated with nausea, constipation, diarrhea, abdominal pain, and urinary tract infection.

Less Likely (*Out of 100 people, 4 to 20 people may have this happen.)*

- High blood pressure, nose and throat infection, urinary tract infection, headache, constipation, upper respiratory tract infection, joint pain, diarrhea, fast heartbeats, stomachache, feeling tired, a decrease of vision, eye pain, lower abdominal pain, nausea, pain in the groin or genitals, tearing of eyes, lip edema, and vomiting.

Rare but Serious *(Out of 100 people, occurs in 3 or fewer people and may require staying at the hospital; or may be irreversible, long-term, life-threatening or fatal.)*

- Blindness, kidney stones, bladder infection, vaginal infection, and prostate cancer.

<u>Reproductive and Breastfeeding Risks</u>
Taking part in this research study can affect an unborn baby. You should not become pregnant or impregnate someone while on this study. If you or your partner can become pregnant, you need to use birth control. Check with the researcher about approved birth control methods to use while in this study.

You should not breastfeed a baby while on this study.

Unknown Risks to the Developing Embryo or Fetus (an unborn baby)
If you are pregnant, or become pregnant during participation in this research, the study drug might involve risks to an embryo or fetus, which are currently unknown. It is important that you contact the researcher immediately if you believe you might be pregnant.

6. Common Medical Procedures Performed for Research Purposes and Risks

The procedures listed below are often part of routine care for a person with your condition. They are not experimental procedures. That said, for this study these procedures and their risks are research-related. This means they are being *repeated* or performed *more frequently* for this study. These common procedures and their risks should be the same as when performed outside this study.

Study Procedure	Related Risks
Physical Exam: We will measure your height, weight and vital signs (heart rate and blood pressure).	This does not have any physical risks.
Medical History Review: We will ask you about your medical and surgical history. We will also ask about your smoking and alcohol habits, physical activity, menopausal history (females only), and your physical activity.	This does not have any physical risks. This does not have any physical risks. This does not have any physical risks.
Questionnaire: You will be asked to complete QOL questionnaires. We think it should take about 15 minutes to complete the questionnaires. For Female Participants: The FSFI questionnaire will ask you to respond to sensitive questions about your sexual health/activity.	Some questions may make you feel uncomfortable or embarrassed. The questionnaire will be labeled with a unique study number. This will link your identity so that only the research team can recognize you. This does not have any physical risks.
Electrocardiogram (ECG): This test is often called an ECG or EKG. This test measures the electrical activity of the heartbeat. It does this by using electrodes (disposable, sticky adhesive discs). The discs are placed on the skin of your chest. Questionnaire.	Removing the disposable sticky discs from your skin may cause minor skin discomfort, redness, or irritation. This includes pulling on the skin/hair during removal of the patches. This hair may be shaved before a patch is placed on your chest. There is a risk of allergic reaction.
Active Standing Test: This is a standard test for POTS patients. Under careful supervision, heart rate and blood pressure are measured after resting lying down, then immediately upon standing and after 1, 2, 3, 4, and 5 minutes of standing if possible.	This test may bring on symptoms of POTS and some people may feel unwell or faint.

Ambulatory Blood Pressure Monitoring (ABPM): intermittently records blood pressure.	Discomfort from inflation of cuff; skin irritation or a mild rash on the arm that usually goes away after removal of the cuff.
7-Day Mobile Cardiac Telemetry Patch: continuously records and stores heartbeats that are analyzed by certified cardiac technicians. Chest.	Skin irritation or redness related to prolonged placement of 7-day Mobile Cardiac Telemetry patch. The patch will be removed, and new ones will be placed on a different site. Removing the disposable sticky discs from your skin may cause minor skin discomfort or irritation. This includes pulling on the skin/hair during removal of the patches. This hair may be shaved before a patch is placed on your chest. There is a risk of allergic reaction.

7. Whether Research Results Will Be Shared With Participants

Imaging Procedures
The imaging procedure(s) in this study are being done for research purposes. However, they will be done following standard clinical imaging techniques. The imaging results may be shared with you. They may be placed in your Cedars-Sinai medical record.

Unanticipated Incidental Findings
We will contact you using the last contact information you gave if, unexpectedly, we find results that suggest potentially clinically relevant medical information. We may suggest you talk with your treating physician about possible additional clinical testing to further evaluate the research finding. You and/or your insurance would pay for any additional testing and any related treatment.

8. Reasons Participation May Be Stopped by the Researcher or Sponsor

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. If your participation is stopped early, the study doctor will discuss next steps with you. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.
- Pregnancy.

9. Voluntary Participation and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of

benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

You can decide not to take part in this study. You have other choices. For example, you may choose:
- To be treated following the usual clinical approach such as taking medications to treat and/or control your POTS associated hypotension.
- To take part in a different study at Cedars-Sinai or elsewhere, if one is available.
- To not be treated.

The study team will discuss these options and their risks and benefits with you. You may also choose to discuss these with your treating physician.

10. Confidentiality Protections

General Confidentiality

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:
- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitors the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

Sharing Information or Samples

We might share your information and/or research samples collected in this study. The information shared may include genomic data and health data or samples that could be used in future genomic research. It might be shared with other researchers at Cedars-Sinai, other researchers outside of Cedars-Sinai, or third-party commercial entities for future research without additional informed consent from you. In some cases, your information and/or

specimens may be submitted to a database or repository for future research. These databases and repositories have safeguards to prevent inappropriate access to and use of the information and specimens. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai. However, there is a remote possibility that someone could identify you.

Clinical Trials Website
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

11. Research-Related Illness or Injury

Contact in Case of Illness or Injury
Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. As needed, your study doctor will treat you or refer you for treatment. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research-related illness or injury?
Cedars-Sinai has no plans to pay for costs associated with the treatment of research-related injury or illness. We will make every effort to seek reimbursement from your health plan. However, you will be responsible for any deductibles and copayments required under your health plan and for any claims ultimately denied by your health plan. Financial assistance may be available under Cedars-Sinai's Financial Assistance Program. If you feel that you have had a research-related injury and need financial assistance, please contact the IRB Office at 310-423-3783. You do not waive any of your legal rights by signing this form.

12. Financial Considerations

Costs of Participation
The attached flowchart lists items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the Study Sponsor. Review the flowchart for details.

For items billed to your insurance, you remain responsible for all deductibles, copays and balances under your health benefit plan. If your insurance company does not pay, you will be billed for those charges. If you have questions or concerns about your insurance coverage, you should ask your health benefit plan.

Payment
You will not be paid for taking part in this research study.

Financial Interest in the Research

The principal investigator and institution have no potential financial conflict of interest with this study.

13. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH
FOR CEDARS-SINAI AFFILIATED COVERED ENTITIES[1]

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Using Mirabegron to Increase Blood Pressure in Patients with Postural Orthostatic Tachycardia Syndrome" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☒ Laboratory tests
☐ Pathology reports
☒ Imaging reports (e.g., x-rays or scans)
☒ Doctor/clinic records
☒ Hospital/medical records
☐ Billing records

☒ Photographs or videos of your image

☒ Demographics, which may include, but is not limited to, age, gender identity, race, ethnicity, and/or sexual orientation

☐ Mental health records
☐ Substance abuse records
☐ HIV test results

☒ Other tests or other types of medical information: Questionnaires

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

[1] The **Cedars-Sinai Affiliated Covered Entity ("ACE")** is comprised of covered entities under the common ownership or control of Cedars-Sinai Health System, including Cedars-Sinai Medical Center (CSMC); Cedars-Sinai Medical Care Foundation; Cedars-Sinai Marina Del Rey Hospital (MDRH); Torrance Memorial Medical Center (TMMC); Torrance Health Association, Inc., d/b/a Torrance Memorial Physician Network; Huntington Hospital (HH), and Huntington Medical Foundation.

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.
- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

Table of Visits, Tests and Procedures

Legend
R = Research item/procedure done only for research purposes and their costs are covered by the study. You are not responsible for the costs of these procedures.
S = Standard of care item/procedure that is part of regular care and billed to the patient/insurance. You and your insurance company will be responsible for these costs.

Procedures	Day 1	Eligibility/Baseline visit, in-person	Follow-Up 1, Virtual Visit, 4 weeks after beginning study drug	Follow-Up 2, in-person (8 Week Post Drug Dispensation)	Follow-Up 3 (12wks), Virtual Visit, 4 weeks after stopping study drug
Screening and eligibility		**R**			
Obtain informed consent	**R**				
Medical history/demographics		**R**			
Concomitant Medication Review		**R**			
Vitals		**R**		**R**	
12-lead ECG recording		**R**		**R**	
Active standing test		**R**		**R**	
EQ-5D-5L, (Quality of Life) QOL, Duke Activity Status Index (DASI), Seattle Angina Questionnaire (SAQ), Malmö POTS Score (MAPS), Female Sexual Function Index (FSFI), overactive bladder (OAB) Questionnaires, and PROMIS SF Fatigue 8a		**R**		**R**	
Ambulatory (SKNA) recording and symptom diary		**R**		**R**	
24-hour ambulatory blood pressure monitoring (ABPM)		**R**		**R**	
Mirabegron [PO]		**R**			
Virtual Visit			**R**		**R**
Assess for safety endpoint and adverse events			**R**	**R**	**R**
Complete case report forms		**R**	**R**	**R**	**R**
Randomization		**R**			
Hospitalization		S			
Outpatient office visit		**R**		**R**	

Signature Page

Consent Form for Research and Authorization
for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

Signature by the Investigator
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date

Signature by the Interpreter/Witness
(Signature of an interpreter is only required when enrolling a non-English-speaking subject with the assistance of an interpreter and IRB-approved "short form" consent processes. The witness may be any person who is conversant in both English and the language of the non-English-speaking subject, such as a certified hospital interpreter, study staff, a family member or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.

Signature of a witness is required when an English-speaking subjects who has been determined to have capacity to consent is unable to read or physically sign the consent form, but choses to indicate via a "mark" or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred and that the individual verbally consented to participate in the research.)

Interpreter/Witness name (please print)	Signature	Date