PHA 2024 Research Room Studies

	Study Title	Study Description	Criteria to Participate	Research Room Activities
1	A Natural History Study of Novel Biomarkers in Pulmonary Arterial Hypertension (PAH) Researcher: Michael Solomon, MD	Researchers are performing this study to: – Learn more about how the disease process changes overtime in order to allow for earlier diagnosis and new treatment pathways.	<u>Inclusion Criteria</u> – WHO Group 1 Pulmonary Hypertension – Patients 18 years or older – Ability to provide informed written consent <u>Exclusion Criteria</u> – Pregnant or breastfeeding women – Age less than 18 years – Inability to provide informed written consent	– Researchers will discuss the study with potentially interested participants and share written information. – Contact information will be collected from interested participants for future involvement. – Estimated time commitment: 15 minutes per participant for an informal discussion.
2	A Pilot Study of the Effect of Spironolactone Therapy on Exercise Capacity and Endothelial Dysfunction in Pulmonary Arterial Hypertension (PAH) Researcher: Michael Solomon, MD	Researchers are performing the study to: – Test whether an investigational drug improves disease symptoms. The study will include questionnaires, blood collection, and tests of heart and lung function at a later date.	<u>Inclusion criteria</u> – WHO Group 1 (PAH) except those with cirrhosis and portal hypertension or with active infection. – Age 18 or older – Ability to provide informed written consent. – Not pregnant <u>Exclusion criteria</u> – Known or suspected allergy to spironolactone – Pregnant or breastfeeding – Age < 18 years Inability to provide informed written consent for participation in the study	– Researchers will discuss the study with potentially interested participants and share written information. – Contact information will be collected from interested participants for future involvement. – Estimated time commitment: 15 minutes per participant for an informal discussion.

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3	Characterizing Roles and Perspectives of Caregivers in Pulmonary Hypertension Researcher: Hilary DuBrock, MD	A caregiver is an individual who provides support to a person who needs help taking care of themselves. Caregivers of patients with pulmonary hypertension (PH) may assist with medications, transportation, emotional support and other forms of support. Little is known about the role of caregivers in PH. We are performing this study to improve our understanding of PH patients' and caregivers' perspectives on the role of caregiving in PH to identify ways to best support caregivers.	Inclusion criteria – Self-reported diagnosis of Pulmonary Hypertension – Age ≥ 18 years – At least 1 caregiver age ≥ 18 years Exclusion Criteria – Inability to complete survey in English	– Participants will complete a survey. – A QR code and link will be available. – Researcher will provide a tablet for participants without access to a cell phone or their own electronic device. – Estimated time commitment: 5-10 minutes.
4	Sexual Health Assessment in Patients with Pulmonary Hypertension Using Validated Sexual Health Instruments Researcher: Meredith Kaplan	By incorporating discussions about sexual health into the management of PAH, healthcare providers can demonstrate a patient-centered approach that addresses patients' needs beyond their medical condition. This study utilizes validated surveys to start these conversations between providers, patients, and their partners. Our central aim is to assess the effectiveness of validated sexual health tools on patients with PAH and compare these results with their overall perception of their sexual function.	Inclusion criteria – Subjects with a historical PH diagnosis that fall under any classification PH Group – Patients must know which group and subgroup of PH and the approximate date of diagnosis (the PHA cohort). – Male or female adults (>18 years old) at the enrollment date – Willing and able to sign a written informed consent before all study-related procedures. Exclusion Criteria – Not knowing the group and/or subgroup of PH, date of diagnosis, and treatment (PHA cohort). – Patients < 18 years old. – Individuals with significant cognitive impairment that prevents them from fully understanding the questionnaires or providing informed consent.	– Participants will complete a paper survey. – Estimated time commitment: 15 minutes

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5	The MObile Health InterVEntion in Pulmonary Arterial Hypertension (MOVE PAH) Study Researcher: Evan Brittain, MD	The goal of this clinical research study is to evaluate how increasing daily step counts in individuals with pulmonary arterial hypertension (PAH) can affect quality of life and 6- minute walk distance. All participants will be provided a new Fitbit device and asked to wear the device for approximately 28 weeks and to complete a series of questionnaires and perform 3 remote 6-minute walk tests. Participants will be compensated a total of $500 for completing all study procedures.	<u>Inclusion criteria</u> – Adults aged 18 or older. – Diagnosed with idiopathic, heritable, or associated (connective tissue disease, drugs, or toxins) pulmonary arterial hypertension (PAH), or PAH due to simple congenital heart disease (i.e. atrial septal defect). – WHO functional class I-III. – Forced vital capacity >65% predicted with no or minimal interstitial lung disease. <u>Exclusion Criteria</u> – Prohibited from normal activity due to wheelchair bound status, bed bound status, reliance on a cane/walker, activity-limiting angina, activity-limiting osteoarthritis, or other condition that limits activity. – Pregnancy – Diagnosis of PAH etiology other than idiopathic, heritable, or associated – Functional class IV heart failure – Requirement of >2 diuretic adjustments in the prior three months – Preferred form of activity is not measured by an activity tracker (swimming, yoga, ice skating, stair master, or activities with wheels such as bicycling or rollerblading)	– Researchers will review eligibility criteria and introduce possible participants to the device. – Researchers will obtain a release of medical information to confirm a PAH diagnosis prior to performing informed consent. – Estimated time commitment: 10 minutes – QR code will be provided
6	Activity Monitoring in Pulmonary Hypertension Researcher: Evan Brittain, MD	Researchers want to understand if someone's daily activity level (measured in steps) can tell us who is more likely, or less likely, to get sick over time. We will ask you to wear a device that tracks your movements and heart rate and we will ask you questions about your quality of	<u>Inclusion criteria:</u> – Adults aged 18 or older. – Individuals diagnosed with pulmonary hypertension by hemodynamics and expert clinical diagnosis.	– Researchers will explain the study and will familiarize potential participants with the device and how the device interacts with their smartphone. – Researchers will assess eligibility criteria and perform the consent

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		life and health. The device is called a Fitbit, which will be referred to as the device. You will be involved in this study for 3 years. You will be asked to wear the device four times total, for 12 weeks at a time. There will be a baseline monitoring period, followed by monitoring periods once a year for 3 years. There will be no in-person study visits. Participants will be compensated a total of $350 for completing all study monitoring periods.	<u>Exclusion criteria:</u> – Pregnancy – Hospitalization within the prior 3 months – Orthopedic limitations that preclude 6-minute walk testing	and enrollment process. Full eligibility will be confirmed after review of clinical records. – Estimated time commitment: 10-20 minutes – QR code will be provided
7	Risk and Resilience in Pulmonary Arterial Hypertension and Genetically Susceptible Individuals (RARE-PAH) Study Researcher: Dr. Anna Hemnes, Dr. Eric Austin, Dr. Evan Brittain Study Coordinator: Kelly Burke, RN **BLOOD DRAW REQUIRED**	It is currently unknown why some at-risk individuals with the BMPR2 gene develop PAH and others do not. We plan to study these genes, and how they influence the development of PAH and the resilience against developing PAH. This study seeks individuals with HPAH **and** their family members to participate. Identification of gene changes, hormonal and blood abnormalities, and how these work together will help in understanding the disease process and may lead to improved therapy. The study will be conducted over the course of 3 years with three visits. Participants in this study will receive $100 per visit and up to $300 total for all three visits.	<u>Inclusion criteria:</u> – Children and Adults, aged 13-80 – Diagnosed with heritable PAH, defined according to standard criteria. – WHO functional class I-III – Stable PAH-specific medication regimen for 3 months prior to enrollment. Subjects with only a single diuretic adjustment in the prior 3 months will be included. Adjustments in IV prostacyclin for side effect management are allowed. – **Unaffected Mutation Carriers:** Healthy participants with a known or unknown heritable gene mutation and normal pulmonary pressure and RV function on echo <u>Exclusion criteria (cont. on next page)</u> – Prohibited from normal activity due to wheelchair bound status, bed bound status, reliance on a cane/walker, activity-limiting angina, activity-limiting osteoarthritis, or other condition that limits activity.	– Researchers will explain the study and have eligible participants complete an electronic questionnaire. – Researchers will perform the consent and enrollment process and take patient vitals. – Under the supervision of the researchers, eligible enrolled patients will undergo a blood draw with phlebotomy team. – QR code will be provided – Estimated time commitment: 15 minutes for questionnaire. – Additional time commitment: one remote study visit a year, for three years

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			– Pregnancy – Diagnosis of PAH etiology other than heritable – Functional class IV heart failure. – Requirement of > 2 diuretic adjustment in the prior three months.	
8	Genomics of Pulmonary Vascular Disease Researcher: Micheala Aldred, PhD **BLOOD DRAW REQUIRED**	Many people with PH have changes in their mitochondria - the "batteries" that power our cells. The goal of our research is to understand how these changes occur. We have preliminary evidence that variation in our DNA (genetic material) might contribute to this. We plan to collect blood samples in order to measure the function of the mitochondria and try to identify genetic variants that may increase the risk of developing PH.	<u>Inclusion criteria</u> – All PH patients (Groups 1-5) – Age 18 or older – Support persons and caregivers can participate as controls <u>Exclusion criteria</u> – Age < 18 years	– Researchers will perform the consent and enrollment process with eligible participants. – Under the supervision of the researchers, eligible enrolled patients will undergo a blood draw with phlebotomy team. – Estimated time commitment: 20 minutes for enrollment and blood draw.