INTRODUCTION:
The SARS-CoV-2 virus which causes COVID-19 has created a global pandemic. Remdesivir and dexamethasone are the only therapies that have shown efficacy in a clinical trial to date, and efficacy appears to be limited to subsets of patients. According to the Centers for Disease Control, as of October 20th, approximately 8.5 million Americans have been diagnosed with COVID-19 resulting in over 221,000 deaths, and it is likely that these numbers are under reported. As our communities begin to enter various phases of reopening, it is inevitable that cases and mortalities will continue to rise. There is still an incredible need for safe and effective treatment options for COVID-19, specifically for hospitalized inpatients as these individuals are at the highest risk for progression to severe disease and death. SARS-CoV-2 convalescent plasma represents a readily available and viable treatment option for COVID-19; however, it has not been scientifically proven to have clinical benefit.

STUDY SUMMARY:
• Title: The Passive Immunity Trial for Our Nation (PassItOn)
• Goal: To determine if anti-SARS-CoV-2 convalescent plasma is a safe and effective therapy for COVID-19
• Study Design: Multicenter, blinded, placebo-controlled randomized clinical trial
• Principal Investigators: Todd Rice, MD, MSC & Wesley Self MD, MPH
• Intervention Group Treatment: 1 unit of SARS-CoV-2 convalescent plasma infused intravenously
• Control Group Treatment: 250 mL of Lactated Ringer’s with multivitamins, which visually resembles plasma, infused intravenously
• Randomization: Eligible participants are randomized 1:1 convalescent plasma vs. control
• Sample Size: 1000 participants
• Primary Outcome: COVID-19 7-point Ordinal Clinical Progression Outcomes Scale on Study Day 15

MULTICENTER START-UP TIMELINE:
7/16
- Submitted Supplement Request
- Received NOA NCATS
8/12
- (EDO) Expression of Interest Webinar
- Community Engagement Meeting Held w/ 60 CTSA Attendees
8/18
- Day 0
9/1
- Day 10
9/22
- Day 26
9/28
- Day 30
10/2
- Day 34
10/20
- Day 50

NCATS/CTSA INFRASTRUCTURE LEVERAGED:
• TIN FDP-CTSA (standardized subaward contract)
• sIRB (VUMC’s IREx)
• TIN/PI webinar
• VUMC’s REDCap data management system
• VUMC/RICT Research Match
• VUMC/RICT eConsent
• VUMC/RICT Community Engagement Studios

ENGAGED SITES:
• Vanderbilt University Medical Center*
• University of Colorado-Denver*
• University of Utah*
• Our Lady of the Lakes Medical Center
• University of Mississippi
• University of Washington*
• Newton-Wellesley Hospital**
• University of Minnesota: Twin Cities*
• State University of New York-Buffalo*
• University of Kansas*
• Virginia Commonwealth University*
• Ohio State University*
• University of Maryland*
• University of New Mexico*
• Scripps Research Institute*
• Medstar Health Research Institute
• Sentara/Eastern Virginia Medical School
• Loyola University*
• University of Arizona-Phoenix
• University of Florida*
• University Kentucky Research Foundations*
• Rochester General Hospital
• Cleveland Clinic
• University of Arkansas*
• Intermountain Healthcare**
• Beth Israel Deaconess**
• Mercy Health - Muskegon
• University of Chicago*
• Lankenau Hospital – Mainline Health
• Meharri Medical College
• Kootenai Health – Coeur d’Alene
• Mercy One- North Iowa Medical Center
• University of New Mexico
• Scripps Research Institute
• Medstar Health Research Institute
• Sentara/Eastern Virginia Medical School
• Loyola University
• University of Arizona-Phoenix
• University of Florida
• University Kentucky Research Foundations
• Rochester General Hospital
• Cleveland Clinic
• University of Arkansas
• Intermountain Healthcare
• Beth Israel Deaconess
• Mercy Health - Muskegon
• University of Chicago
• Lankenau Hospital – Mainline Health
• Meharrri Medical College
• Kootenai Health – Coeur d’Alene
• Mercy One- North Iowa Medical Center

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