

SUBMITTED BY: STEPHEN M. LANIER, PH.D., VICE PRESIDENT FOR RESEARCH
REPORT ON WAIVERS APPROVED
TO BOARD STATUTE 2.41.01.140

BACKGROUND

One research project required a petition to waive Statute 2.41.01.140 because a publication delay of up to 105 days was needed to permit the primary institution on the project, Vanderbilt University, to file any patent applications and to meet the obligations of the sponsor, the National Institutes of Health, and drug providers involved in this study. This waiver has been approved by the Vice President for Research to allow acceptance of the relevant grant or contract, acting in accordance with the University’s research policy on restricted and proprietary research.

OVERVIEW

This project required a waiver to Board Statute 2.41.01.140 to allow acceptance of a publication delay up to 105 days to permit the filing of any desired patent applications and to meet obligations of the National Institutes of Health and drug providers involved in the study. The waiver allowed acceptance of the study, “CONNECTS Master Protocol for Clinical Trials targeting macro-, micro-immuno-thrombosis, vascular hyperinflammation, and hypercoagulability and renin-angiotensin-aldosterone system (RAAS) in hospitalized patients with COVID-19 (ACTIV 4d RAAS),” by Robert Sherwin, M.D, clinical associate professor of emergency medicine in Wayne State’s School of Medicine, from Vanderbilt University Medical Center.

The goal of this clinical study is to find effective strategies for inpatient management of patients with laboratory confirmed SARS-CoV-2 infection who are on oxygen therapy using a randomized, placebo-controlled approach with agents to target the host response in COVID-19. These agents have potential beneficial effects on restoring the renin-angiotensin-aldosterone system (RAAS) balance in COVID-19 which would result in hastening recovery and preventing progression to critical illness, multiorgan failure, or death. Results of this study will aide in generating new and innovative therapies for CoVID-19 and guide future CoVID-19 or other coronavirus research.