

SUBMITTED BY:

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**REPORT ON WAIVERS APPROVED
TO BOARD STATUTE 2.41.01.140**

BACKGROUND

Four research projects required a petition to waive Statute 2.41.01.140 because of review restrictions on publishing the research results. These waivers have 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

JANSSEN RESEARCH & DEVELOPMENT

Two waivers were issued for research funded by Janssen Research & Development, protocol FLZ3001, titled, "A Phase 3 Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of Pimodivir in Combination With the Standard-of-care Treatment in Adolescent, Adult, and Elderly Hospitalized Patients With Influenza A Infection." This project required a waiver to Board Statute 2.41.01.140 to allow acceptance of a publication delay up to 165 days based on guidelines flowed down from the sponsor's prime agreement with the U.S. Government Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA).

The purpose of this study is to evaluate the clinical and virologic benefit of the study drug in combination with Standard-of-Care (SOC) treatment compared to placebo in combination with SOC treatment. This study will evaluate efficacy/safety of this treatment on adolescent (13 to 17 years), adult (18 to 65 years), and elderly (greater than [$>$] 65 but less than or equal to [\leq] 85 years) hospitalized patients with influenza A infection. Compounding the study drug on top of SOC has the potential to reduce or limit the morbidity and mortality for high risk Influenza A patients in addition to improving clinical outcomes. Ultimately, if the therapy being studied is deemed ineffective, the results could guide future influenza research.

Two additional waivers were issued for research funded by Janssen Research & Development, protocol FLZ3002, titled, "A Phase 3 Randomized, Double-blind, Placebo-controlled, Multi-center Study to Evaluate the Efficacy and Safety of Pimodivir in Combination With the Standard-of-care Treatment in Adolescent, Adult, and Elderly Non-hospitalized Patients With Influenza A Infection who Are at Risk of Developing Complications." This project required a waiver to Board Statute 2.41.01.140 to allow acceptance of a publication delay up to 165 days also based on guidelines flowed down from the sponsor's prime agreement with the U.S. Government Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA).

Similar to the protocol FLZ3001 study, the purpose of this study is to evaluate the clinical and virologic benefit the study drug used in combination with Standard-of-Care (SOC) treatment compared to placebo in combination with SOC treatment for those with Influenza A. However, this study is aimed at adolescent (13 to 17 years), adult (18 to 65 years), and elderly (greater than [$>$] 65 but less than or equal to [\leq] 85 years) non-hospitalized patients with influenza A infection who are at risk of developing complications. Compounding the study drug on top of SOC has the potential to reduce or limit the morbidity and mortality for high risk Influenza A patients in addition to improving clinical outcomes. This study's main objective is also to determine if the addition of the study drug to SOC treatment of Influenza A patients improves outcomes and would aide in generating new and innovative therapies for Influenza A.

These projects are all led by John Wilburn, M.D., assistant professor – clinical, Department of Emergency Medicine, School of Medicine.