

SUBMITTED BY:

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

BACKGROUND

Three research projects required a petition to waive Statute 2.41.01.140 because of review restrictions on publishing the research results. 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

GLOBAL BLOOD THERAPEUTICS

This waiver allowed acceptance of a clinical study agreement with Global Blood Therapeutics to Michael Callaghan, M.D., associate professor – clinical, Department of Pediatrics, School of Medicine. The study, "An Open Label Extension Study of GBT440 Administered Orally to Patients with Sickle Cell Disease Who Have Participated in GBT440 Clinical Trials," aims to determine the long term effect of the study drug on patients with Sickle Cell Disease. It is believed that this mechanism of action will continue to improve symptoms in Sickle Cell Disease and the information obtained from this study will enhance current knowledge of the treatment.

This project required a waiver to Board Statute 2.41.01.140 because the sponsor requires that all resulting publication submissions and presentations are delayed up to 180 days in order to allow the sponsor to file patent applications and to establish and preserve the sponsor's proprietary rights.

A second waiver was approved to allow acceptance of an additional clinical study agreement with Global Blood Therapeutics to Michael Callaghan, M.D. This waiver allows the study, "A Phase 3, Randomized, Double-Blind, Placebo Controlled Study of Voxelotor (GBT440) in Pediatric Participants with Sickle Cell Disease and an Open-label Study in Infants with Sickle Cell Disease (HOPE Kids 2)." The main purpose of this research study is to determine the effect of the study drug compared to a placebo in increasing red blood cell counts and reducing the severity of the symptoms of Sickle Cell Disease in pediatric patients. Dr. Callaghan is performing this study in conjunction with two other Global Blood Therapeutics studies using the same study drug in the hopes of creating a well-rounded understanding of the study drug and expanding knowledge about its' effects on Sickle Cell Disease in patients of all age groups.

This project required a waiver to Board Statute 2.41.01.140 because the sponsor requires that all resulting publication submissions and presentations are delayed up to 180 days in order to allow sponsor to file patent applications and to establish and preserve the sponsor's proprietary rights.

MICHIGAN TALENT AGENCY

This waiver allowed acceptance of a project from the Michigan Talent Agency in the State of Michigan Department of Talent and Economic Development to Dr. Monica Brockmeyer, associate provost, for the project, "Warrior Vision and Impact Program: Coaching and Progress Monitoring." The main purpose of this project is to provide support services to Wayne State University undergraduate students. No research will be conducted utilizing these funds.

This project required a waiver to Board Statute 2.41.01.140 because the sponsor requires that all resulting publications need prior sponsor approval. However, there will not be any publications resulting from this project.