

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

THE ALLIANCE OF AUTOMOBILE MANUFACTURERS

This waiver allowed the acceptance of a continuation of a restricted research project with the Alliance of Automobile Manufacturers, a Delaware not-for-profit corporation, to Dr. Liying Zhang, associate professor of Biomedical Engineering in the College of Engineering. The study is aimed at developing and refining state-of-the-art models for neurotrauma research and mathematical simulation techniques. The project will provide an improved understanding that can be translated to the human head model and in turn will significantly improve our ability to predict injury using the computer model. The injury criterion developed from this research can be applied to assess the performance of any safety device/equipment related to head protection such as helmet and headgear in any unclassified or unrestricted work. In addition, the improved head model can be used to help establish new test methods using virtual computer model simulations before building the actual physical prototypes to reduce the cost associated with actual prototype and testing.

HISPANIC COMMUNITY HEALTH STUDY/STUDY OF LATINOS

This waiver allowed the acceptance of a restricted research proposal with the Hispanic Community Health Study/Study of Latinos, Study of Latinos – Investigation of Neurocognitive Aging, to Dr. Wassim Tarraf, assistant professor of occupational therapy in the Applebaum College of Pharmacy & Health Science. The Hispanic Community Health Study/Study of Latinos is a multi-center epidemiologic study supported by the contracts with the National Heart, Lung and Blood Institute. This multi-center observational longitudinal health study is designed to document health status in four Hispanic communities around the United States and to obtain baseline measures of pulmonary function, cardiovascular function, metabolic status, oral health and measures of neurocognitive and psychological functioning. Approximately 16,000 adults ages 18 to 74 years will be enrolled at these four field centers over a 36 month period, and will be followed for 36 months to assess health outcomes. Dr. Tarraf is the WSU site principal investigator and the lead statistician.

The purpose of this research is to learn about the health of Hispanic/Latinos in the United States and to identify causes of disease of these populations. The data collected is intended to promote the discovery of specific genetic loci acting as risk (or protective) factors for health-related traits. Use of these data to conduct non-genetic research is prohibited. The data may not be used to investigate individual participant genotypes for the purpose of identifying participants. Investigation of relatedness among individuals and of genomic composition in terms of genetic ancestry may be used as tools to detect and

characterize genetic risk factors for health-related traits. However, publications based on these data may not provide specific pedigree structures, results concerning sensitive issues such as non-paternity, or in any way compromise the anonymity of study participants directly or indirectly. Publication of genetic associations with traits should focus on specific genetic variants rather than overall genetic ancestry profiles. Publications may not report results that could be considered as stigmatizing to an individual or group.

AURINIA PHARMACEUTICALS, INC.

This waiver allowed the acceptance of a restricted research proposal with Aurinia Pharmaceuticals, Inc. for the study, A Randomized, Controlled Double-blind Study Comparing the Efficacy and Safety of Orevo (voclosporin) (23.7 mg twice daily) with Placebo in Achieving Renal Response in Subjects with Active Lupus Nephritis. Dr. Yahya Mohamed Osman, assistant professor of internal medicine in the School of Medicine, is the principal investigator on the study. The study will determine the efficacy and safety of Orevo taken orally twice a day in 324 subjects with active lupus nephritis compared to a placebo. The restrictions applied to the publication of results will be that Aurinia Pharmaceuticals will publish results at the end of 2019.