

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and the Patient-Centered Outcomes Research Institute (PCORI)

Action Requested: Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects while reviewing the Proposal Approval Form which then triggered a review by the UMOR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by the Committee and agreed to by the parties involved.

This proposed research agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professor Christopher Friese is an employee of the University of Michigan (“University”), and a Member of the Board of Directors for the Patient-Centered Outcomes Research Institute (“PCORI”). The law permits such an Agreement provided it is disclosed to the Board of Regents (“Regents”) of the University of Michigan and approved in advance by a 2/3 vote.

Background:

Dr. Christopher Friese, a Professor in the School of Nursing, is a Member of the Board of Directors for a non-profit institute called PCORI (the “Company”). The Company wishes to fund a project entitled, “Observational Analyses of Second-Line Pharmacological Agents in Type 2 Diabetes” (ORSP #21-PAF00284) in the Department of Internal Medicine – Metabolism, Endocrinology & Diabetes, under the direction of Dr. William Herman. The purpose of this project is to examine the benefits of newer classes of drugs as second line therapies for people with type 2 diabetes (T2DM) to determine whether the benefits of these drugs outweigh the potential inconvenience, side effects, and cost.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately three (3) years. The amount of funding support will not exceed \$1,121,663. Since research projects are often amended, this Agreement includes provisions for changes in time and scope. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

Impact of the Agreement:

The Agreement will support an effort by Dr. Herman to use his expertise and University laboratories, as well as other University resources, to help address the uncertainty faced by patients with type 2 diabetes and their care providers when choosing among drugs and potentially defining subgroups of people who are more or less likely to benefit.

Recommendations:

This matter has been reviewed and approved by the UMOR Conflict of Interest Review Committee. In light of this disclosure and our finding that the Agreement was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the University's entering into this Agreement with the Patient-Centered Outcomes Research Institute.

Respectfully submitted,



Rebecca Cunningham
Vice President for Research

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