

Submitted by: Margaret E. Winters, Provost and Senior Vice President for Academic Affairs

UNIVERSITY CONTRACT TO ENTER INTO A CONTRACT WITH TOTAL RENAL RESEARCH INC., DBA DAVITA CLINICAL RESEARCH, A SUBSIDIARY OF DAVITA, INC., A COMPANY WHICH HAS A SCHOOL OF MEDICINE'S FACULTY MEMBER AS ONE OF THEIR MEDICAL DIRECTORS

Recommendation

The Administration recommends the Board of Governors authorize the President or his designee to contract with Total Renal Research Inc., dba DaVita Clinical Research, a subsidiary of DaVita, Inc. ("DaVita"), to perform clinical research services for up to 200 study subjects over an 18-month period at a total price of \$65,576.

Background

Dr. Pramod Khosla, Associate Professor, Department of Nutrition and Food Science, Wayne State University ("WSU") is the Principal Investigator of the PATCH Study, a study of hemodialysis patients, which is sponsored by the Malaysian Palm Oil Board (the "Study"). Due to the large number of patient subjects (approximately 400) required for the Study, the desired practicality of contracting with dialysis clinics that are geographically close to WSU, and the need to fulfill the Study requirements in a timely manner, Dr. Khosla prefers that the services of several regional clinics be used for the Study, including two DaVita clinics. At present, there are at least seven dialysis clinics being used to provide clinical services for the Study and Dr. Khosla would like to add the DaVita Kresge Dialysis site in Detroit and the DaVita PDI-Highland Park site in Highland Park, for a total of at least nine dialysis clinics.

During the proposal stage for the Study, the WSU Human Investigation Committee recommended that Dr. Khosla appoint a medical doctor as Co-Investigator of the Study with a specialty in nephrology who would be medically responsible for patients if problems arise regarding possible drug interactions or side effects of the study drug. Therefore, Dr. Khosla appointed Dr. James Sondheimer, MD, Associate Professor, Department of Internal Medicine, Wayne State University, as Co-Investigator who is a specialist in nephrology.

In addition to Dr. James Sondheimer holding current employment at Wayne State University and the WSU Physician Group ("WSUPG"), by way of a contract between DaVita, or one of its affiliated companies, and WSUPG, he is also the Medical Director of DaVita's Greenview Dialysis Center located in Southfield Michigan. The Medical Director's duties are set forth in 42 CFR 494.150; it is not a fiscal corporate governance role.

As part of his WSU position, Dr. Sondheimer's role in the Study will include clinical research activities including the recruitment of subjects; monitoring for adverse events/drug interactions and intervening as necessary; and liaising with nephrologists at other participating dialysis clinics. In addition, as part of his WSUPG role, Dr. Sondheimer may be the attending nephrologist on Study subjects, in which case he would be providing general nephrologic care as he would for any of his patients. At this time, Dr. Sondheimer will have no involvement in the Study as part of his

role as Medical Director for the DaVita Greenview site since that site is not currently being proposed to be used for the Study. Even if the DaVita Greenview site were to be used for the Study, Dr. Sondheimer's role as Medical Director would solely be to ensure that the Study is conducted safely and he would not otherwise benefit from the Study being conducted at that site.

Michigan Conflict of Interest law requires specific sunshine procedures in order for a University employee, or a company that is owned by a University employee or for which a University employee is employed or is an officer, to contract directly or indirectly with the University:

- (A) The employee must disclose any pecuniary interest in the contract to the Board and the disclosure must be made a matter of record in the Board's proceedings.
- (B) The contract must be approved by a vote of not less than two-thirds of the full membership of the Board in open session.
- (C) The Board's minutes must report:
 - (i) The name of each party involved in the contract.
 - (ii) The terms of the contract, including duration, financial consideration between the parties, facilities or services of the public entity included in the contract, and the nature and degree of assignment of employees of the public entity for fulfillment of the contract.
 - (iii) The nature of any pecuniary interest.

If the Board approves this Recommendation, the minutes will report as follows:

The Board of Governors authorized the President, or his designee, to enter into an agreement for DaVita Clinical Research to provide up to \$65,576 in clinical research services to Wayne State University.

- (i) The parties involved in the contract are Wayne State University and Total Renal Research Inc., dba DaVita Clinical Research, a subsidiary of DaVita, Inc. ("DaVita").
- (ii) The contract will provide:
 - (a) Scope: DaVita will enroll and provide clinical research services for up to 200 patient subjects. Such services shall include activities such as phlebotomy, order entry, witness ingestion of oral medication and drug accountability.
 - (b) Duration: The contract will be for 18 months (approximately. from June 15, 2016 through December 15, 2017).

(c) Financial Consideration: Wayne State University will pay DaVita \$327.88 per patient up to a total of 200 patients and not to exceed \$65,576.

(d) Locations: The contracted services will be performed at the DaVita Kresge Dialysis site in Detroit and the DaVita PDI-Highland Park site in Highland Park.

(iii) Dr. Sondheimer's only pecuniary interest is that of his position as the Medical Director of DaVita's Greenview Dialysis Center, which position is contracted for between his employer, Wayne State University Physician's Group ("WSUPG") and DaVita (or one of its affiliated companies) and for which WSUPG it is compensated by DaVita; neither Dr. Sondheimer nor WSUPG will receive any type of additional compensation as a result of this contract. In addition, neither Dr. Sondheimer nor any of his family members has any stock or other financial interest in DaVita or any of its parent companies or subsidiaries.

Also of note are Dr. Stephen Migdal and Dr. Robert Provenzano. Dr. Stephen Migdal, MD, is Professor in the Department of Internal Medicine, Wayne State University. Through the earlier-mentioned contractual arrangement between WSUPG and DaVita, Dr. Migdal serves as the Medical Director of DaVita's Kresge, Highland Park, Redford, and Motor City Dialysis sites and compensation for such services is rendered to WSUPG. Other than serving in this role for DaVita at the Kresge and Highland Park sites, Dr. Migdal is not involved in the study contemplated by the agreement between Wayne State University and DaVita, nor was he involved in selecting the sites for the study or negotiating the agreement between Wayne State University and DaVita.

Dr. Robert Provenzano, MD, is a voluntary clinical professor of medicine, Wayne State University. Dr. Provenzano serves as DaVita's Vice President, Medical Affairs and also as the Medical Director of DaVita Hospital Services. Dr. Provenzano is not involved in the study contemplated by the agreement between Wayne State University and DaVita, nor was he involved in selecting the sites for the study or negotiating the agreement between Wayne State University and DaVita.