

## **Institutional Conflict of Interest Management and Monitoring Plan: Optera Therapeutics Corp.**

The University of Texas MD Anderson Cancer Center (MD Anderson) is a Party to a Research and Protocol Development Agreement (Development Agreement) with Optera Therapeutics Corp. (Optera) and Berkley Lights, Inc. (BLI) pursuant to which MD Anderson, BLI, and Optera will collaborate in the conduct of a clinical study titled "Phase II Study Assessing the Effect of BK Specific CTL Lines Generated by ex vivo Expansion in Patients with BK Virus Infection and JC Virus Infection" (Study) as well as other research studies.

The Board of Regents of The University of Texas System (Board) on behalf of MD Anderson is a party to several license agreements with Optera (License Agreements) whereby Board has licensed or will license MD Anderson technologies related to Licensed Subject Matter. The Board on behalf of MD Anderson is also party to a Stockholder Agreement of Optera whereby Board was a party to the formation of Optera as a corporation.

Under the Development, License, and Stockholder Agreements, MD Anderson acquired an equity interest in Optera equal to fifty percent (50%) of the outstanding stock of Optera, will receive royalty income, and MD Anderson, BLI, and Optera will collaborate in the conduct of studies.

MD Anderson's Agreements, and the equity and royalties received under the Agreements, create an institutional financial conflict of interest in relation to the research to be conducted by MD Anderson, including research involving the Licensed Subject Matter (Studies).

Because MD Anderson is committed to the protection of human subjects and the effective management of its financial conflict of interest in relation to its research activities, MD Anderson has implemented an Institutional Conflict of Interest Management and Monitoring Plan (Plan) to manage and monitor the conflict of interest with respect to MD Anderson's conduct of the Studies. The Plan has been approved by the President of MD Anderson and the Executive Vice Chancellor for Health Affairs for The University of Texas System (EVC) and has been implemented by MD Anderson.

The Plan requirements include:

- MD Anderson employees who have a financial interest in Optera and will be involved in the conduct of the Studies will have a personal conflict of interest management plan covering their involvement in the Studies.
- Disclosure of MD Anderson's financial interest to participants of Studies, to all members of the research teams who will work on the Studies, and in all publications and oral presentations concerning the Studies,
- Posting of this summary on MD Anderson's public website,
- Referral of any concerns/complaints related to MD Anderson's compliance with the Plan, or its financial conflict of interest, to The University of Texas System,
- Recusal of any MD Anderson Institutional Decision Maker, who has a financial relationship with Optera or its known affiliates, from any negotiations with respect to any agreements or purchasing decisions,
- Oversight of Studies by an external Institutional Review Board (External IRB), including reporting to the External IRB by MD Anderson's Investigational New Drug (IND) Office when applicable,
- Engagement of a non-MD Anderson ethicist (External Ethicist) to address any questions or concerns that participants in the Studies may have pertaining to the MD Anderson financial interest and conflict of interest,
- Supply a copy of the Plan to the External IRB and External Ethicist,
- Review of safety and efficacy data of Studies that are clinical trials by an external and independent Data Safety Monitoring Board (External DSMB),
- Use of multi-institutional trials with a non-MD Anderson lead principal investigator for Studies that are a Phase III or Phase II clinical trial aimed at gaining FDA approval under a new drug or biological license application,

- Monitoring activities related to the manufacture of Investigational Agents, if required for the Studies, by MD Anderson's IND Office,
- Providing the EVC copies of all reports received from the External DSMB, as applicable,
- Reporting to the EVC by an External Contract Research Organization on Studies that are IND-enabling preclinical studies,
- Review and revision of the Plan as necessary with any amendments requiring EVC approval, and
- Annual review of MD Anderson's compliance with the Plan by The University of Texas Systemwide Compliance Officer, with a written report of the review from the External DSMB to be provided to the EVC.

*Prepared April 16, 2018*