

Institutional Conflict of Interest: Oncoceutics

MD Anderson and Oncoceutics, Inc. (Oncoceutics) are parties to a Strategic Alliance and Research Collaboration Agreement (the "SARC Agreement") pursuant to which MD Anderson and Oncoceutics are collaborating on the conduct of two clinical trials involving Oncoceutic's drug, ONC201. Under the SARC Agreement, MD Anderson has a right to share in commercialization proceeds resulting from a license or sale of ONC201 or the sale of Oncoceutics, and Oncoceutics also has an option to buy-out its financial obligations under the SARC Agreement. Because of MD Anderson's financial interest in the success of the ONC201, MD Anderson has a conflict of interest in regards to its conduct of the two clinical trials involving ONC201.

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 ONC201 clinical trials. 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:

- Oversight of MD Anderson's two ONC201 clinical trials by an external, independent Institutional Review Board (IRB),
- Review of safety and efficacy data by an external, independent Data Safety Monitoring Board (DSMB),
- Periodic reporting to the EVC.
- Disclosure of the MD Anderson financial interest to all clinical trial patients, to all members of the ONC201 clinical trials' research teams, and in all publications and oral presentations concerning the ONC201 clinical trials,
- Posting of this summary on MD Anderson's public website.
- Engagement of a non-MD Anderson ethicist to address any questions or concerns that ONC201 clinical trial participants' may have pertaining to the MD Anderson financial interest and conflict of interest,
- Referral of any concerns/complaints related to MD Anderson's compliance with the Plan, or its financial conflict of interest, to the Office of General Counsel for The University of Texas System.
- 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 to be provided to the EVC.

MD Anderson will modify the Plan, if and when necessary, to address any subsequent matters implicating the integrity of the Clinical Trials and to comply with any additional requirements deemed necessary by the EVC to ensure the integrity of the Clinical Trials.

Last updated 3/29/2017