Amended and Restated Institutional Conflict of Interest Management Plan: Oncoceutics, Inc.

The University of Texas MD Anderson (MD Anderson) and Oncoceutics, Inc. (Oncoceutics) are parties to Strategic Alliance & Research Collaboration Agreements (Agreements) pursuant to which MD Anderson and Oncoceutics will collaborate in the conduct of research studies involving Oncoceutics’ drugs, ONC201 and ONC212 (Studies).

Under the Agreements, MD Anderson has a right to share in commercialization proceeds resulting from royalties from a license of ONC201 and/or ONC212, sale of ONC201 and/or ONC212, and the sale of Oncoceutics. Oncoceutics will pay MD Anderson for costs related to ONC201 and ONC212 drug supplies for the Studies, and milestone payments for expenses related to conducting ONC212 studies. Oncoceutics has an option to buy-out its financial obligations under the Agreements. Because of MD Anderson’s financial interest in the success of ONC201 or ONC212, MD Anderson has a conflict of interest in regards to its conduct of the 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 Amended and Restated 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:

- Oversight of Studies by an external Institutional Review Board (External IRB), including reporting to the External IRB by MD Anderson’s IND Office when applicable,
- Disclosure of MD Anderson’s financial interest to all participants in the 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 Oncoceutics or its known affiliates from negotiations with respect to any agreements or purchasing decisions,
- 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 of 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 PI for Studies that are Phase III or Phase II clinical trials aimed at gaining FDA approval under a new drug or biological license application,
- Prompt reporting of any serious adverse events experienced by participants in the Studies to the EVC,
- 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.