Institutional Conflict of Interest: Cellenkos, Inc.

The University of Texas MD Anderson Cancer Center (MD Anderson) and Cellenkos, Inc. (Cellenkos) are parties to a License and Strategic Development Agreement (Agreement) whereby MD Anderson licensed certain rights related to T-Regulatory Cells (Licensed Subject Matter) to Cellenkos and will conduct research related to the Licensed Subject Matter. Under this Agreement, the Board of Regents of The University of Texas System, on behalf of MD Anderson, received equity in Cellenkos. This equity will be held, managed and disposed of by The University of Texas Investment Management Company for, and on behalf of, the UT System and MD Anderson. Additionally, MD Anderson will receive funding to conduct research related to the Licensed Subject Matter. MD Anderson's equity interest creates an institutional financial conflict of interest in relation to the research to be conducted by MD Anderson involving the Licensed Subject Matter.

Because MD Anderson is committed to the integrity of research, 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 financial conflict of interest with respect to MD Anderson's conduct of the research involving the Licensed Subject Matter. 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.

Below are the required elements of the Plan:

- Oversight of MD Anderson's clinical trials by an external, independent Institutional Review Board (IRB).
- Conduct phase II and/or phase III clinical trials aimed at gaining FDA approval, as multiinstitutional trials with the lead principal investigator being from an institution other than MD Anderson.
- Review of safety and efficacy data by an external, independent Data Safety Monitoring Board (DSMB).
- Disclosure of MD Anderson's financial conflict of interest to all clinical trial participants, to all members of the Cellenkos research teams, and in all publications and oral presentations concerning the research related to the Licensed Subject Matter.
- Oversight of MD Anderson's preclinical studies by an external Contract Research Organization (CRO).
- Periodic reports sent to the EVC or to the Institutional Conflict of Interest Committee (ICOIC) that will be organized by MD Anderson.
- Disclosure of this summary on MD Anderson's public website.

- Engagement of a non-MD Anderson ethicist to address any questions or concerns that Cellenkos clinical trial participants' may have pertaining to the MD Anderson financial 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 University of Texas System.
- Prohibition against any MD Anderson Institutional Decision Maker with a financial relationship with Cellenkos being involved in any negotiations with Cellenkos or its known affiliates.
- 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 and reports from the CRO and DSMB 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 studies and clinical trials and to comply with any additional requirements deemed necessary by the EVC to ensure the integrity of the studies and clinical trials.

Last updated 4/6/2017