

Institutional Conflict of Interest: Ziopharm/Intrexon

MD Anderson, Ziopharm, and Intrexon are parties to a licensing agreement in connection with which the Board of Regents of The University of Texas System (“Board”), on behalf of MD Anderson, received equity in Ziopharm and Intrexon. This equity will be held by, and will be managed and disposed of by the University of Texas Investment Management Company on behalf of the Board and MD Anderson. In addition, MD Anderson and Ziopharm and Intrexon are parties to a Research and Development Agreement under which MD Anderson will conduct certain clinical trials involving Intrexon and Ziopharm (the “Intrexon/Ziopharm Clinical Trials”).

MD Anderson’s equity interest in Intrexon and Ziopharm creates an institutional financial conflict of interest in relation to the Intrexon/Ziopharm Clinical Trials to be conducted by MD Anderson. 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 Intrexon/Ziopharm 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), has been implemented by MD Anderson and applies to all Intrexon/Ziopharm Clinical Trials.

The Plan requirements for the Intrexon/Ziopharm Clinical Trials include:

- Oversight by a non-MD Anderson Institutional Review Board (IRB)
- Review of safety and efficacy data by an appropriately qualified non-MD Anderson Data Safety Monitoring Board (DSMB)
- Periodic reporting to the EVC, including prompt reporting to the EVC of any serious adverse events related to the Intrexon/Ziopharm Clinical Trials and providing to the EVC copies of all reports received from the DSMB
- Disclosure of the MD Anderson financial interest to all Intrexon/Ziopharm Clinical Trial subjects, to all members of the Intrexon/Ziopharm Clinical Trials’ research teams, and in all publications and oral presentations concerning the Intrexon/Ziopharm 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 Intrexon/Ziopharm Clinical Trial participants’ may have pertaining to the MD Anderson financial interest and conflict of interest
- Monitoring of manufacturing and testing activities by MD Anderson’s Investigational New Drug Office; monitoring information will be included in written monitoring reports provided to the non-MD Anderson IRB
- Prohibiting any MD Anderson Institutional Decision Maker with a financial relationship with Intrexon and/or Ziopharm from participating in any negotiations with Intrexon and/or Ziopharm including with respect to any sponsored research agreement
- 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

A complete copy of the Plan may be obtained from MD Anderson's Institutional Compliance Office (Phone: 713-745-6636; email: Institutional_Compliance@mdanderson.org).

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