

## **Institutional Conflict of Interest Management and Monitoring Plan: Navire Pharma, Inc.**

The University of Texas MD Anderson (MD Anderson) and Navire Pharma, Inc. (Navire) are parties to a Collaboration and License (Agreement) pursuant to which MD Anderson and Navire will collaborate on the conduct of research and development of products involving Licensed Subject Matter licensed to Navire. Under this Agreement, the Board of Regents of The University of Texas System, on behalf of MD Anderson, received equity in Navire. 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. Because of MD Anderson's Agreement and equity received under the Agreement, MD Anderson has a conflict of interest in regards to research conducted by MD Anderson involving 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 Navire and will be involved in the conduct of the Studies, will have a personal conflict of interest management plan covering their involvement of the Studies.
- Disclosure of MD Anderson's financial conflict of interest to 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 Navire or its known affiliates from 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 Phase III or Phase II clinical trials 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,
- 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 July 16, 2018*