

Institutional Conflict of Interest Management and Monitoring Plan: Tvardi Therapeutics, Inc.

The University of Texas MD Anderson (MD Anderson) and Tvardi Therapeutics, Inc. (Tvardi) are parties to research agreements (Agreements) to conduct research studies (Studies). Dr. David Tweardy, Head of the Division of Internal Medicine, is an Institutional Decision Maker as defined by MD Anderson Institutional Policy #ADM1273, Institutional Conflict of Interest Policy for the University of Texas MD Anderson Cancer Center and Its Institutional Decision Makers. Dr. Tweardy has a financial interest with Tvardi. Dr. Tweardy's financial interest in Tvardi, combined with his position as an Institutional Decision Maker with MD Anderson, creates an institutional conflict of interest related to any 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.

Prohibitive measures in the Plan include:

- Dr. Tweardy will not be involved in any negotiations with Tvardi or its known affiliates with respect to sponsored research agreements, purchasing decisions, or any other type of agreement;
- Dr. Tweardy will not be involved in the approval or execution of contracts or agreements involving Tvardi on behalf of MD Anderson, and MD Anderson will use alternate arrangements for the processing of such agreements involving Tvardi for final approval and execution;
- Dr. Tweardy will not be involved in any relevant discussions at Tvardi and MD Anderson except as specifically invited by MD Anderson as a content expert; and
- Dr. Tweardy will not supervise anyone (1) participating in discussions involving any existing or proposed business relationships or research collaboration involving Tvardi and MD Anderson or (2) who also has a financial interest with Tvardi.

The Plan requirements include:

- MD Anderson employees who have both a financial interest in Tvardi 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 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 Tvardi 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 MD Anderson's Institutional Conflict of Interest Committee and MD Anderson Institutional Compliance, with a report of such review provided to The University of Texas System Ethics Officer.

Prepared/Updated 12/27/2019