

Institutional Conflict of Interest Management and Monitoring Plan: Obsidian Therapeutics

The University of Texas MD Anderson (MD Anderson) and Obsidian Therapeutics (Obsidian) are parties to a Collaborative Research & Option Agreement (CROA) and a License Agreement (Agreement). Under the collaboration, each party will own improvements to its technology. MD Anderson granted Obsidian an option for a future field of use license in certain intellectual property created at MD Anderson. Obsidian exercised its option for a license. Accordingly, MD Anderson/Board of Regents and Obsidian entered into a “field of use” license agreement whereby UT granted license rights to Obsidian in certain existing and future intellectual property created at MD Anderson (Licensed Technology).

Under the CROA, MD Anderson received preclinical collaboration funding and an upfront intellectual property option fee. MD Anderson received no upfront license fee but may receive future development milestones and sales milestones. Under the Agreement, MD Anderson may also receive royalties on sales of products and a portion of sublicense fees received by Obsidian.

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 both a financial interest in Obsidian 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 Obsidian or its known affiliates from negotiations with respect to any agreements or purchasing decisions.
- For any Clinical Trials, no creator of the licensed technology may serve as a Principal Investigator or Co-Investigator, nor may they enroll patients on said Clinical Trials.
- Third party monitoring of the eligibility criteria and safety and efficacy data for any Clinical Trial.
- 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.
- 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.

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