Institutional Conflict of Interest Management and Monitoring Plan: Cure51

The University of Texas MD Anderson (MD Anderson) and Cure51 (Company) are parties to a Strategic Alliance Agreement (Agreement). Under the Agreement, the Parties will work to identify biomarkers and novel therapeutic targets associated with response and outcomes from exceptional survivors in multiple cancer types. MD Anderson and Cure51 may also explore a Joint Venture to exploit any potential products developed utilizing joint results, limited exclusively to novel drug design.

Under the Agreement, MD Anderson will receive funding for research and equity, and in the event of the creation of a Joint Venture, milestone and royalty payments. MD Anderson's Agreement and receipt of equity and research funding create an institutional financial conflict of interest in relation to the clinical research studies to be conducted by MD Anderson (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 both a financial interest in Cure51 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 Cure51 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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