

Institutional Conflict of Interest Management and Monitoring Plan: Astellas Pharma, Inc.

The University of Texas MD Anderson (MD Anderson) and Astellas Pharma, Inc. (Astellas) are parties to an Option and Development Fund Agreement (Agreement) pursuant to which MD Anderson and Astellas will collaborate on the conduct of certain research and development activities with respect to the h8F4 Technology (Studies).

Under the Agreements, MD Anderson has a right to Option fees, expenses incurred for IND enabling studies and manufacture of h8F4 Technology for clinical trials, and for development of h8F4 Technology in acute myelogenous leukemia and other tumors. One of the Option fees to be paid to MD Anderson by Astellas creates an institutional conflict of interest.

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 Amended and Restated 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 Astellas 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 and the financial interest of individual creators and inventors of the h8F4 Technology involved in the conduct of the Studies, including a disclosure of the percentage share of payments payable to such individuals, to participants in the Studies,
- Disclosure of MD Anderson's financial conflict of interest, the financial interest of any individual creators and inventors of the h8F4 Technology involved in the conduct of the Studies, and the Plan to all members of the research teams who will work on the Studies,
- Supply information about the consent process to the External IRB, which will include observation by a non-MD Anderson external ethicist of the consent process for the first patient receiving the first dosing on a Clinical Trial,
- Prior to administration of the first dosing to the first patient on a clinical trial, review and confirm the eligibility of that patient by a non-MD Anderson oncologist with the appropriate expertise and no financial interest in Astellas,
- 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 Astellas 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 11-16-18