

Institutional Conflict of Interest Management and Monitoring Plan: Spectrum Pharmaceuticals, Inc.

The University of Texas MD Anderson (MD Anderson) and Spectrum Pharmaceuticals, Inc. (Spectrum) are parties to an Exclusive Patent and Technology License Agreement (Agreement) pursuant to which MD Anderson and (Spectrum) will collaborate on the conduct of at least two Phase II clinical trials and possibly other trials involving MD Anderson's Licensed Technology.

Under the Agreements, MD Anderson has a right to an upfront license fee, patent prosecution expenses, annual maintenance fees, and a running royalty on sales of Poziotinib products. MD Anderson also has the right to both various regulatory and commercial milestone payments and a milestone payment paid either (1) after the dosing of the first patient with a Licensed Technology in a Phase III clinical study or (2) after the receipt of a "breakthrough therapy designation" from the FDA for a Licensed Technology, which may be paid to MD Anderson in the form of equity at Spectrum's election.

John Heymach, M.D., Chair of Thoracic Head and Neck Medical Oncology, is an Institutional Decision Maker and is entitled to a portion of the license income from the Agreement. This financial relationship has been determined to be a conflict of interest.

Because of MD Anderson's and Dr. Heymach's financial interests discussed above, MD Anderson has a conflict of interest in regards to the current and any future research 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.

Prohibitive measures in the Plan include:

- Dr. Heymach will not be involved in any negotiations with Spectrum or its known affiliates with respect to sponsored research agreements, purchasing decisions or any other type of agreement,
- Dr. Heymach will not serve as a principal investigator (PI) for the Studies,
- Dr. Heymach will not share confidential information unless expressly authorized,
- Dr. Heymach will not be involved in the approval or execution of contracts or agreements involving Spectrum on behalf of MD Anderson and the use of alternate arrangements for the processing of such agreements involving Spectrum for final approval and execution,
- Dr. Heymach will not be involved in any relevant discussions at Spectrum and MD Anderson except as specifically invited by MD Anderson as a content expert, and
- Dr. Heymach will not will supervise anyone participating in discussions involving any existing or proposed business relationships or research collaboration involving Spectrum and MD Anderson.

The Plan requirements include:

- MD Anderson employees, who have a financial interest in Spectrum 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 Licensed 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 Licensed Technology involved in the conduct of the Studies, and the Plan to all members of the research teams who will work on the Studies,

- Disclosure of MD Anderson’s financial conflict of interest in all publications and oral presentations concerning the Studies,
- If a Phase III Clinical Trial occurs before the FDA designates a Licensed Technology as a “breakthrough therapy, MD Anderson will supply information about the consent process that will include observation by a non-MD Anderson external ethicist of the consent process for the first patients who will receive the first dosing on said Phase III Clinical Trial to the External IRB,
- If a Phase III Clinical Trial occurs before the FDA designates a Licensed Technology as a “breakthrough therapy, the first patient’s Clinical Trial eligibility will be reviewed and confirmed by a non-MD Anderson oncologist with appropriate expertise and no financial interests in Spectrum, prior to administration of the first dosing of the first patients on said Phase III Clinical Trial upon which MD Anderson will receive milestone payments from Spectrum,
- 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 Spectrum 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 Compliance Office and Institutional COI Committee, which will be reported to The University of Texas System Ethics Officer.

Prepared April 17, 2019