Institutional Conflict of Interest Management and Monitoring Plan: Moleculin Biotech, Inc.

The University of Texas MD Anderson (MD Anderson) and Moleculin Biotech, Inc. (Moleculin) are parties to Patent and Technology License Agreements (Agreements) pursuant to which MD Anderson and Moleculin will collaborate in the conduct of research studies involving Licensed Subject Matter licensed to Moleculin (Studies).

Under the Agreements, MD Anderson has a right to receive (i) a royalty on net sales of products under Licensed Subject Matter, (ii) certain fees related to the Licensed Subject Matter and the licenses, and (iii) payments with respect to milestones achieved by products under Licensed Subject Matter. Because of MD Anderson’s financial interest in the success of the Licensed Subject Matter, MD Anderson has a conflict of interest in regards to its conduct of the 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 a financial interest in Moleculin and will be involved in the conduct of the Studies, will have a personal conflict of interest management plan covering their involvement in 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 Moleculin 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 February 27, 2018