

Institutional Conflict of Interest Management and Monitoring Plan: Novel Anti-Infective Technologies, LLC (NAT)

The University of Texas MD Anderson (MD Anderson) and Novel Anti-Infective Technologies (NAT) are parties to a Patent and Technology License Agreement (Agreement) pursuant to which MD Anderson and NAT will collaborate on the conduct of research studies with respect to the Licensed Subject Matter licensed to NAT under the Agreement (Studies).

Under the terms of the Agreement, NAT will pay MD Anderson expenses incurred in filing, prosecuting, enforcing and maintaining patent rights, license documentation fees, annual maintenance fees, assignment fees, royalties on net sales of licensed products, milestone payments, investment equity, and a percentage of sublicensing consideration.

Issam Raad, MD, Department Chair of Infectious Diseases, is an MD Anderson Institutional Decision Maker who serves on NAT's Board of Directors and has a 50% ownership interest in NAT. This financial relationship has been determined to be a conflict of interest. As such, MD Anderson has taken steps to manage this conflict of interest.

Joel Rosenblatt, PhD, Director of Infectious Diseases, reports to Dr. Raad, serves on NAT's Board of Directors and has a 28% ownership interest in NAT. This financial relationship has been determined to be a conflict of interest.

The financial relationship between MD Anderson and NAT and the financial relationship between Dr. Raad and NAT create an institutional financial conflict of interest in relation to the Studies conducted by MD Anderson.

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

Requirements in the Plan include:

- MD Anderson employees, including Drs. Raad and Rosenblatt, who have a financial interest in NAT, NAT subsidiaries, or NAT sublicensees 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 Dr. Raad's personal and institutional management plans to individuals directly supervised by or in the line of reporting to Dr. Raad,

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- Altered reporting structure for individuals directly supervised by or in the line of reporting to Dr. Raad when these individuals are responsible for negotiations or decisions with NAT or have a financial interest in or a financial relationship with NAT,
- Prompt disclosure by Dr. Raad to the MD Anderson Conflict of Interest Committee with respect to existing business relationships or research collaborations involving NAT and MD Anderson,
- Disclosure of MD Anderson's, Dr. Raad's, and any investigator's financial conflict of interest to all Study participants, to all members of research teams who will work on the Studies, and in all publications and oral presentations concerning these Studies,
- Posting of this summary on MD Anderson's public website,
- Referral of any concerns/complaints related to MD Anderson's or Dr. Raad's compliance with the Plan, or its financial conflict of interest, to the Office of General Counsel for The University of Texas System,
- Oversight of Studies by an external, independent Institutional Review Board (External IRB), including reporting to the External IRB by MD Anderson's Investigational New Drug (IND) Office when applicable,
- Costs for oversight of Studies, that consist of human subjects research conducted for and with NAT and for which Dr. Raad will be involved, by an External IRB will be paid utilizing funds from NAT, and/or Dr. Raad's research account,
- Engagement of a non-MD Anderson ethicist (External Ethicist) to address any questions or concerns that participants in the Studies may have pertaining to MD Anderson's or Dr. Raad's financial 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 PI 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,
- Acknowledgement by Dr. Raad that his primary appointment is with and his primary responsibility is to MD Anderson,
- 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.