

## Institutional Conflict of Interest: Bio-Path, Inc

MD Anderson and Bio-Path, Inc (Bio-Path) are parties to a licensing agreement in connection with which the Board of Regents of The University of Texas System ("Board"), on behalf of MD Anderson, received equity in Bio-Path, Inc. This equity will be held, managed and disposed of by the University of Texas Investment Management Company for and on behalf of the UT System and MD Anderson. Additionally, MD Anderson will receive royalties on net sales of licensed products and milestone payments upon filing of new drug applications and regulatory approvals of licensed products. Bio-Path will pay MD Anderson a fee upon assignment of its assets that include Licensed Subject Matter to another entity. MD Anderson will be a participating site for a multi-site phase II trial involving BP1001 (Trial) that is included in the Licensed Subject Matter. MD Anderson's equity interest, and rights to payments related to Licensed Subject Matter create an institutional financial conflict of interest in relation to research being conducted by MD Anderson involving the Licensed Subject Matter, including the Trial.

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 using Bio-Path licensed subject matter. 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:

- Oversight of MD Anderson's clinical trials by an external, independent Institutional Review Board (IRB),
- Conduct of phase III studies, or phase II studies trials aimed at gaining FDA approval, as multi-institutional trials with the lead principal investigator being from an institution other than MD Anderson,
- Review of safety and efficacy data by an external, independent Data Safety Monitoring Board (DSMB),
- Disclosure of the MD Anderson financial interest to all clinical trial patients, to all members of the Bio-Path research teams, and in all publications and oral presentations concerning the Bio-Path Studies,
- Oversight of MD Anderson's preclinical studies by an external Contract Research Organization (CRO),
- Periodic reporting to the EVC or to the Institutional Conflict of Interest Committee (ICOIC) that MD Anderson is organizing,
- Posting of this summary on MD Anderson's public website,
- Engagement of a non-MD Anderson ethicist to address any questions or concerns that Bio-Path clinical trial participants' may have pertaining to the MD Anderson financial interest and conflict of interest,
- Referral of any concerns/complaints related to MD Anderson's compliance with the Plan, or its financial conflict of interest, to the Office of General Counsel for The University of Texas System,
- Prohibition against any MD Anderson institutional decision maker with a financial relationship with DNatrix being involved in any negotiations with DNatrix or its known affiliates, 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 and reports from the CRO, and DSMB to be provided to the EVC.

MD Anderson will modify the Plan, if and when necessary, to address any subsequent matters implicating the integrity of the Studies and to comply with any additional requirements deemed necessary by the EVC to ensure the integrity of the Clinical Trials.

*Last updated 3/29/2017*