

Institutional Conflict of Interest: OncoResponse, Inc

MD Anderson and OncoResponse, Inc (OncoResponse) are parties to a Strategic Alliance and Research Collaboration Agreement (SARC Agreement) pursuant to which MD Anderson and OncoResponse are collaborating on the conduct of pre-clinical and clinical studies (Studies) using OncoResponse's Platform Technology. Under the SARC Agreement, MD Anderson and OncoResponse will establish a Joint Scientific Committee to serve as an advisory committee for all Studies.

Under the SARC Agreement, MD Anderson will receive equity in OncoResponse. This equity will be held, managed and disposed of by the University of Texas Investment Management Company on behalf of the UT System Board of Regents and MD Anderson. Additionally, MD Anderson will receive royalties on net sales of drugs developed under one or more of the Studies and milestone payments upon approval of each Biological License Application by the FDA and achievement of specified net sales amounts of all Drug Products. Because of MD Anderson's financial interest in the success of the OncoResponse SARC Agreement, 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 under the OncoResponse SARC Agreement. 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),
- Oversight of MD Anderson's preclinical studies by an external Contract Research Organization (CRO)
- Review of safety and efficacy data by an external, independent Data Safety Monitoring Board (DSMB),
- Periodic reporting to the EVC or to the Institutional Conflict of Interest Committee (ICOIC) that MD Anderson is organizing,
- Disclosure of the MD Anderson financial interest to all clinical trial patients, to all members of the OncoResponse research teams, and in all publications and oral presentations concerning the OncoResponse Studies,
- Posting of this summary on MD Anderson's public website.
- Engagement of a non-MD Anderson ethicist to address any questions or concerns that OncoResponse 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.
- 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.