Academic Affiliation Agreement with TGen

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Submitted to:
University of Arizona Senior Vice President for Business Affairs and Chief Financial Officer
University of Arizona Senior Vice President for Legal Affairs and General Counsel

Copies to:
Institutional Internal Audit Review Board
Audit Committee, Arizona Board of Regents
University of Arizona President

Issued by:  Sara J. Click, CPA, Chief Auditor
    Internal Audit Department
Academic Affiliation Agreement with TGen

Summary

Our review of the University of Arizona’s ("UA") use of the Translational Genomics Research Institute ("TGen") Academic Affiliation Agreement ("affiliation agreement") with the Arizona Board of Regents, for itself and on behalf of the three Arizona universities, was included in our approved Fiscal Year ("FY") 2014 Audit Plan. It was expected that efficient and effective administration of this affiliation agreement would help support UA’s Never Settle strategy at the time to “improve internal business processes to facilitate and leverage community and industry relationships with the University.” This was our first review of an affiliation agreement.

Background: In 2004, the presidents of the Arizona Board of Regents, UA, Northern Arizona University, and Arizona State University signed an affiliation agreement with TGen. Quoting from the affiliation agreement, its stated purposes were to:

- (a) Provide a framework within which TGen as an independent §501(c)(3) research organization, and the Universities, can work together and use their respective resources in a mutually reinforcing manner in order to coalesce and expand the spectrum of genomics, bioscience and biotechnology research and development conducted in Arizona;
- (b) Support TGen’s efforts to attract and retain world-class scientists;
- (c) Support the Universities’ efforts to attract world-class bioscience faculty and to conduct and participate in cutting-edge biomedical research, teaching and applications; and
- (d) Establish equitable financial arrangements among the parties, and administrative processes conducive to achieving these goals.

TGen was established in 2002 and moved into its headquarters at the Phoenix Biomedical Campus in 2004. According to TGen’s website, it is a non-profit organization focused on developing earlier diagnostics and smarter treatments that relies on state, federal, and private gifts and grants to carry out its research.

The agreement described shared benefits available to faculty of both TGen and UA. If a UA employee worked for TGen, TGen would reimburse UA for the time, and vice versa. Each institution would apply separately for sponsored research unless the parties agreed to pursue a project jointly. In addition, UA would be the grantee for all externally sponsored research for which the principal investigator is a UA employee and vice versa. This allowed each party to maintain its own sponsored research compliance program without needing to rely on the other party’s compliance controls.
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The original agreement made each university president a member of the TGen Board of Directors with full voting rights. However, the affiliation agreement’s second amendment, effective July 1, 2009, changed university representation to a seat on the TGen Board of Governors for each president or his or her designee. According to the TGen website, UA’s President is a member of the Board of Governors.

The original term of the agreement was 10 years. In January 2014, the third amendment to the agreement was signed by the President of ABOR and the Chief Operating Officer of TGen and extended the term through December 31, 2014.¹

Review Objective: Our primary review objective was to determine how the governance structure for research collaboration and compliance with TGen was utilized.

Scope: The scope of this review included the original Academic Affiliation Agreement, dated January 15, 2004, between TGen and the Arizona Board of Regents, on behalf of Arizona State University, Northern Arizona University and UA, and the three subsequent amendments (“affiliation agreement”).

Methodology: Our review objective was accomplished by performing the following:

- Reviewing the affiliation agreement and three amendments;
- Interviewing UA staff to understand the history of the agreement and how the affiliation is used today, including meeting and/or emailing with:
  - Interim Vice President for Research and Associate Vice President for Research²;
  - Associate Vice President for Research;
  - Associate Vice President for Finance and Administration within the Vice President for Health Sciences office;
  - Deputy Dean for Finance and Business Affairs, College of Medicine Tucson;
  - Associate Dean for Administration and Business Affairs, College of Medicine Phoenix;
  - Associate Dean for Academic and Professional Affairs, College of Pharmacy;
  - Professor, Pharmacology and Toxicology;
  - Assistant Director, Capital Finance, Financial Services Office;

¹ Subsequent to completion of audit fieldwork, the affiliation agreement with TGen expired and it is currently no longer in effect.
² Following completion of this section of the field work, a new Senior Vice President for Research was named and the person we interviewed returned to her role as Associate Vice President for Research.
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• Accountant, Principal, Capital Finance, Financial Services Office;
• Assistant Director, Biomedical and Life Science Licensing, Tech Transfer Arizona; and
• Contracts Analyst, Contracting and Research Services.

- Contacting the State of Arizona Office of the Auditor General to confirm that they had not audited TGen;
- Reviewing records of subcontracts, material transfer agreements, and research plans with TGen held by the Contracting and Research Services (“CRS”);
- Discussing the use of the affiliation agreement with the Vice President for Research Administration, TGen;
- Reviewing TGen and TGen Foundation documents available from the Arizona Corporation Commission and IRS 990 filings available in online databases, identifying UA employees mentioned in the 990, and contacting one UA assistant professor to understand the nature of her work with TGen; and
- Searching federal sponsored research databases for awards to UA researchers that may not have been awarded through UA.

**Conclusion:** The affiliation agreement included broad goals and ideals for collaboration between the three state universities and TGen but did not include specific operational details for how the collaborations would be carried out. UA and TGen representatives met to attempt to work out the details; however, operational procedures were not developed to allow the parties to fully collaborate as the agreement may have intended. Although the affiliation agreement defines the role of “affiliation liaisons” who meet no less than quarterly to advance the purposes of the agreement, we were unable to identify whether these quarterly meetings had occurred.

We did identify one research plan (2012) that was signed between UA and TGen that detailed collaboration between researchers and referenced the affiliation agreement’s terms. We also found one research project that resulted in intellectual property determined to be jointly owned by UA and TGen under the terms of the affiliation agreement (2004). In each case, the agreement was processed through UA’s existing internal control structure: the research plan through CRS and the joint intellectual property through Tech Transfer Arizona.

We did not identify any research projects that were out of compliance with the affiliation agreement’s terms for conducting research. As described in the agreement, each institution applied separately for sponsored research and the entity that employed the principal investigator was the grantee for the sponsored research. Besides the research plan and the joint intellectual property, we did not identify any joint research that was established through...
the affiliation agreement. Based on work performed, we did not identify any instances where UA’s research compliance structure was not utilized for grants awarded to UA researchers.

Due to a number of factors, UA’s use of the affiliation agreement and its collaboration with TGen were not well documented and we were unable to determine the full extent to which this agreement may have been used. Since 2004 when the agreement was signed, there have been a great deal of turnover in positions that may have had knowledge of UA’s work with TGen.

Although we only identified one research plan and one joint intellectual property agreement that specifically incorporated the terms of the affiliation agreement, UA had a number of existing collaboration methods in place and used these to work with TGen. Incoming and outgoing sponsored research subcontracts, material transfer agreements, designated campus colleague affiliations, clinical affiliations for training medical students, and rental agreements were all used to collaborate with TGen during the terms of this agreement. Each collaboration method had its own internal control structure for negotiating, monitoring, and evaluating compliance.

We believe that UA could improve on future affiliation agreements based on the experience with this agreement. Affiliation agreements will likely continue to play a larger role in helping UA fulfill the goals of its strategic plans. These improvements may include:

- Assessing existing collaboration methods, including subcontracts, rental agreements, and designated campus colleague affiliations, to determine whether a new agreement is necessary or whether existing UA methods are adequate;
- Including all relevant UA administrators during the negotiation process;
- Naming affiliation liaisons from both parties who will be designated to develop operational procedures, in order to clarify how the parties will work together to meet the stated goals, and ensuring the named liaisons are aware of the responsibilities and able to communicate as needed;
- Naming the person(s) authorized to make changes or adjustments to the terms of the agreement and requiring that the changes be in writing and, when possible, made through an amendment; and
- Utilizing an existing contract administration department (i.e., CRS or Sponsored Projects Services) or establishing a new process that incorporates strong internal controls, to monitor for compliance throughout the term of the agreement.
According to the Institute of Internal Auditors International Professional Practices Framework, an organization is expected to establish and maintain effective risk management and control processes. These control processes are expected to ensure, among other things, that:

- The organization’s strategic objectives are achieved;
- Financial and operational information is reliable and possesses integrity;
- Operations are performed efficiently and achieve established objectives;
- Assets are safeguarded; and
- Actions and decisions of the organization are in compliance with laws, regulations, and contracts.

Our assessment of these control objectives as they relate to the affiliation agreement with TGen is presented below.

<table>
<thead>
<tr>
<th>General Control Objectives</th>
<th>Control Environment</th>
<th>Review Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achievement of the Organization’s Strategic Objectives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The agreement furthered UA’s strategic objectives.</td>
<td>Reasonable to Strong Controls in Place</td>
<td></td>
</tr>
<tr>
<td>Reliability and Integrity of Financial and Operational Information</td>
<td>Not Applicable</td>
<td></td>
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<tr>
<td>Effectiveness and Efficiency of Operations</td>
<td>Not Applicable</td>
<td></td>
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<tr>
<td>Safeguarding of Assets</td>
<td>Not Applicable</td>
<td></td>
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<tr>
<td>Compliance with Laws and Regulations</td>
<td></td>
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<tr>
<td>• Compliance with research requirements was maintained while working under the terms of this affiliation agreement.</td>
<td>Reasonable to Strong Controls in Place</td>
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/s/
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