EXECUTIVE SUMMARY

**ACTION ITEM:** Disclosure of Substantial Interest of University Employee
Michael E. Hogan, Research Professor, Bio5 Institute, in GUSA, Inc.

**ISSUE:**

Pursuant to Laws 1986 Chapter 240 (A.R.S. Section 15-1635.01), the University of Arizona requests Board approval for University employee, Michael E. Hogan, Ph.D., Research Professor, Bio5 Institute, to establish and maintain a substantial equity interest in GUSA, Inc., a private entity that may license University inventions and/or supply contract funding for research within the University.

**BACKGROUND:**

- The Arizona legislature made provision for university employees to act on behalf of a university while also owning an interest in a private sector business having contractual arrangements with the university (Laws 1986 Ch. 240 Section 2, A.R.S. Section 15-1635.01). The present case has been reviewed by the University and is now presented for Board approval.

- The President of the University of Arizona has approved this request and certifies compliance with the statutory requirements.

- The Institutional Review Committee on Conflict of Interest has reviewed and approved the Enabling Disclosure submitted by Dr. Hogan for GUSA, Inc.

- Professor Hogan is a full-time employee of the University of Arizona. His involvement with GUSA, Inc., will not interfere with his teaching, research, or service duties at the University.

- GUSA, Inc., was founded in Houston in 2001 by Rahul Mitra and Michael E. Hogan to develop and commercialize technology that they invented in 2000 while faculty members at Baylor College of Medicine. GUSA technology is based on the low-cost manufacture of DNA microarrays, a technology patented by Baylor College of Medicine and licensed exclusively to GUSA in 2001.

**CONTACT:** Richard C. Powell (520) 621-3513
Vice President for Research, Graduate Studies and Economic Development
rcpowell@u.arizona.edu
EXECUTIVE SUMMARY

- In 2004, Professor Hogan and GUSA were awarded a Homeland Defense Small Business Innovation Research (SBIR) grant to develop low cost microarrays for human leukocyte antigen (HLA)-based human immunogenetics at the population scale. The Hogan laboratory is a subcontractor on the SBIR grant. Two additional SBIR applications are pending with additional proposed sub-contracts to Professor Hogan’s laboratory.

- Professor Hogan serves as Chief Scientific Advisor to GUSA and in that capacity directs application testing of the HLA microarray technology and assists in the development of SBIR funding opportunities for the technology in the Homeland Defense area.

- The microarray technology was transferred to GUSA in 2001 as an exclusive worldwide license, which will generate royalties to Baylor College of Medicine, once GUSA begins product sales. Under Baylor’s intellectual property sharing plan, Professor Hogan will be granted about 20% of the Baylor royalty stream. Since GUSA products are not yet commercialized, there is no royalty income to date. Professor Hogan has also been granted stock in GUSA amounting to approximately 20% of the founder stock in the company. At present, Professor Hogan does not receive a salary from the company.

- GUSA, Inc., will contribute to the economy of the State of Arizona by providing research support to the University of Arizona. There are no negative consequences to the interests of the State of Arizona.

RECOMMENDATION/CONCLUSION:

RESOLVED: That pursuant to A.R.S. Section 15-1635.01, the University of Arizona be, and hereby is, authorized to permit Dr. Michael E. Hogan to establish and maintain a substantial interest in GUSA, Inc., while continuing his employment at the University of Arizona.
EXECUTIVE SUMMARY

ACTION ITEM: Disclosure of Substantial Interest of University Employee
Michael E. Hogan, Research Professor, Bio5 Institute, in
GenVault, Inc.

ISSUE:

Pursuant to Laws 1986 Chapter 240 (A.R.S. Section 15-1635.01), the University of Arizona requests Board approval for University employee, Michael E. Hogan, Ph.D., Research Professor, Bio5 Institute, to establish and maintain a substantial equity interest in GenVault, Inc., a private entity that may license University inventions and/or supply contract funding for research within the University.

BACKGROUND:

• The Arizona legislature made provision for university employees to act on behalf of a university while also owning an interest in a private sector business having contractual arrangements with the university (Laws 1986 Ch. 240 Section 2, A.R.S. Section 15-1635.01). The present case has been reviewed by the University and is now presented for Board approval.

• The President of the University of Arizona has approved this request and certifies compliance with the statutory requirements.

• The Institutional Review Committee on Conflict of Interest has reviewed and approved the Enabling Disclosure submitted by Dr. Hogan for GenVault, Inc.

• Professor Hogan is a full-time employee of the University of Arizona. His involvement with GenVault, Inc., will not interfere with his teaching, research, or service duties at the University.

• GenVault, Inc., was founded in Carlsbad, California, in 2001 by Mitch Eggers and Michael E. Hogan to develop and commercialize technology that they invented as an outgrowth of their ongoing Genometrix collaboration, a company that they co-founded in Houston, Texas, in 1992 while Hogan was on the faculty at Baylor College of Medicine. GenVault is focusing effort on commercializing the original dry state DNA storage technology (filed as patents in 2001) as a suite of large-scale automation and information technology products.

CONTACT: Richard C. Powell (520) 621-3513
Vice President for Research, Graduate Studies
and Economic Development
rcpowell@u.arizona.edu
EXECUTIVE SUMMARY

- Since 2002, GenVault has been funding a service agreement with the University of Arizona at an annual rate of approximately $200,000 for the Hogan laboratory to validate GenVault technology in useful application areas. In addition, a proposal has been submitted to the Department of Defense Breast Cancer Initiative (with Hogan as principal investigator and Patricia Thompson of the Arizona Cancer Center as co-principal investigator) which, if funded, will support the development of protein storage applications for diagnostic and population-scale risk assessment applications in breast cancer.

- Professor Hogan serves as acting Chief Scientific Advisor to GenVault and a member of its Board of Directors. Professor Hogan holds approximately 2.6% of the total stock in GenVault: 2.5% are founder shares that were awarded in 2001 when the company was formed, and 0.1% are stock options that were awarded in 2004. There is no pending plan to increase the amount of the Hogan stock ownership during the next three years.

- GenVault, Inc., will contribute to the economy of the State of Arizona by continuing its funding of the Hogan laboratory via the service agreement. This support continues to fund the research of undergraduate interns and graduate students in the laboratories of collaborators without any limitation on their ability to use the work for thesis or publication. In addition, GenVault, Inc., has transferred its technology for the purpose of archiving and distributing DNA from tissue sections to the Southern Arizona Veterans Affairs Medical Center, where it is being used as the basis to build a national-scale archiving system. There are no negative consequences to the interests of the State of Arizona.

RECOMMENDATION/CONCLUSION:

RESOLVED: That pursuant to A.R.S. Section 15-1635.01, the University of Arizona be, and hereby is, authorized to permit Dr. Michael E. Hogan to establish and maintain a substantial interest in GenVault, Inc., while continuing his employment at the University of Arizona.
EXECUTIVE SUMMARY

**ACTION ITEM:** Disclosure of Substantial Interest of University Employee
Stuart K. Williams, Director, Biomedical Engineering, and
Leigh B. Kleinert, Research Specialist, in IKEN Tissue Therapeutics, Inc.

**ISSUE:**

Pursuant to Laws 1986 Chapter 240 (A.R.S. Section 15-1635.01), the University of Arizona requests Board approval for University employees, Stuart K. Williams, Ph.D., Director, Biomedical Engineering, and Leigh B. Kleinert, Research Specialist, to establish and maintain a substantial equity interest in IKEN Tissue Therapeutics, Inc., a private entity that may license University inventions and/or supply contract funding for research within the University.

**BACKGROUND:**

- The Arizona legislature made provision for university employees to act on behalf of a university while also owning an interest in a private sector business having contractual arrangements with the university (Laws 1986 Ch. 240 Section 2, A.R.S. Section 15-1635.01). The present case has been reviewed by the University and is now presented for Board approval.

- The President of the University of Arizona has approved this request and certifies compliance with the statutory requirements.

- The Institutional Review Committee on Conflict of Interest has reviewed and approved the Enabling Disclosure submitted by Dr. Williams and Ms. Kleinert for IKEN Tissue Therapeutics, Inc.

- Director Williams and Ms. Kleinert are both full-time employees of the University of Arizona. Their involvement with IKEN Tissue Therapeutics, Inc., will not interfere with their teaching, research, or administrative duties at the University.

- IKEN is a second-generation tissue-engineering company whose mission is to improve vascular health with novel tissue-based therapies. Vascular and cardiovascular therapies are a promising area for commercial biomedical product

**CONTACT:** Richard C. Powell (520) 621-3513
Vice President for Research, Graduate Studies and Economic Development
rcpowell@u.arizona.edu
EXECUTIVE SUMMARY

- development. Successfully addressing one or more major, and presently unmet, medical needs in these areas will produce attractive returns. Tissue engineering efforts are aimed at tissue repair and transplantation, where new tissues are created and implanted to induce physiological changes or remain an active part of the body.

- IKEN is purchasing assets and licenses from distressed tissue-engineering firms and academic institutions, and evaluating them according to commercial market potential, time, cost of pre-clinical and clinical development, costs of commercial development, regulatory compliance, manufacturing cost, patent protection, and availability of excellent scientific, clinical, commercial, and regulatory personnel.

- Dr. Williams is the Vice President of Pre-Clinical Research and a member of the IKEN Scientific Advisory Board. He is a founding member of the corporation and the company has issued 240,000 shares equal to 5% of the total founding member’s shares. Dr. Williams’ responsibilities involve the evaluation of the scientific merits of the intellectual property being considered for licensing by IKEN Tissue Therapeutics, Inc.

- Under Dr. Williams’ supervision, Ms. Kleinert will be responsible for the analysis and modification of clinical and pre-clinical research protocols. Any of Ms. Kleinert’s time spent working on IKEN research at the University of Arizona will be addressed via a sponsored research agreement between the University and IKEN.

- Future research and development programs may emerge as part of the licensing of this tissue-engineering technology. When appropriate, research and development agreements will be executed between IKEN and the University of Arizona to conduct this research.

- IKEN Tissue Therapeutics, Inc., will contribute to the economy of the State of Arizona, by paying license and development fees, licensing royalties, and providing research support to the University of Arizona. There are no negative consequences to the interests of the State of Arizona.

RECOMMENDATION/CONCLUSION:

RESOLVED: That pursuant to A.R.S. Section 15-1635.01, the University of Arizona be, and hereby is, authorized to permit Dr. Stuart K. Williams and Ms. Leigh B. Kleinert to establish and maintain a substantial interest in IKEN Tissue Therapeutics, Inc., while continuing their employment at the University of Arizona.