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President Wayne L. Niederhauser, Co–Chair • Speaker Greg Hughes, Co–Chair
Senator Gene Davis • Senator Ralph Okerlund • Representative Brian S. King • Representative Brad R. Wilson

JOHN M. [illegible] JR., CIA
AUDITOR GENERAL

October 17, 2017

Senator Ann Millner, Chair
Representative Val Peterson, Chair
Education Interim Committee
Utah State Capitol Complex
Salt Lake City, UT 84114

Dear Senator Millner and Representative Peterson:

Enclosed are copies of the legislative audit report #2017-09, *A Review of the Procurement Process for the U of U's Heritage 1K Project*. In accordance with ***Utah Code*** 36-12-8, the Legislative Audit Subcommittee passed a motion referring this audit report to your committee for further review and action as appropriate. The audit report was also referred to *the Higher Education Appropriations Subcommittee*, but your committee is designated as the lead committee, so we would like a response from you.

The Legislative Auditor General and staff have done extensive work and used valuable resources to perform the audit in a professional and thorough manner. We anticipate a response from your committee. Therefore, **for each recommendation to the Legislature**, we ask that your committee reach one of the following conclusions, or some combination of the three, by a motion and a vote:

- Draft legislation for the next Legislative General Session, if applicable
- Conclude that the issues are significant but that more time is needed to develop solutions and consensus
- Conclude that there is insufficient committee support to study the issues further

In addition, **for other (non-legislative) recommendations**, we ask that as part of your oversight role you determine whether appropriate action is being taken to address the audit findings. We ask that you report back to the Audit Subcommittee the conclusion(s) reached by your committee with a summary of the reasons for reaching this (these) conclusion(s).

Thank you for your efforts in this vital legislative role of oversight.

Sincerely,

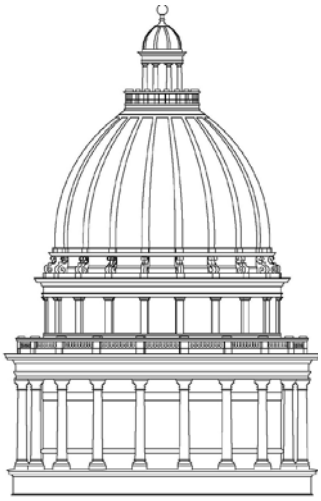
Wayne L. Niederhauser
President of the Senate
Utah State Senate

Gregory H. Hughes
Speaker of the House
Utah House of Representatives

REPORT TO THE

UTAH LEGISLATURE

Number 2017-09



A Review of the Procurement Process For the U of U's Heritage 1K Project

October 2017

Office of the
LEGISLATIVE AUDITOR GENERAL
State of Utah

STATE OF UTAH

Office of the Legislative Auditor General

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Audit Subcommittee of the Legislative Management Committee
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Senator Gene Davis • Senator Ralph Okerlund • Representative Brian S. King • Representative Brad R. Wilson

JOHN M. SCHAFF, CIA
AUDITOR GENERAL

October 17, 2017

TO: THE UTAH STATE LEGISLATURE

Transmitted herewith is our report, **A Review of the Procurement Process for the U of U's Heritage 1K Project** (Report #2017-09). A digest is found on the blue pages located at the front of the report. The objectives and scope of the audit are explained in the Introduction.

We will be happy to meet with appropriate legislative committees, individual legislators, and other state officials to discuss any item contained in the report in order to facilitate the implementation of the recommendations.

Sincerely,

John M. Schaff, CIA
Auditor General

JMS/lm

Digest of
A Review of the Procurement Process For the U of U's Heritage 1K Project

The Heritage 1K (H1K) project was conducted at the University of Utah (University or the U of U) from 2014-16 and consisted of the sequencing of 1,372 genome samples for 1,000 individuals. This project was made possible because of a $12 million donation to the University to sequence samples from the Utah Population Database (UPDB). An audit of H1K was requested because the sequencing was done at a facility owned by the donor, which led to questions of propriety. While this audit does not examine improprieties on the part of the donor, it does raise some concerns with the lack of a competitive bidding process to award the contract and the resulting inefficient use of the donation.

Chapter II
The University Did Not Follow Procurement Statute When Awarding the Genome Sequencing Contract

Utah Code **Requires a Competitive Procurement for Contracts Like Heritage 1K.** Because the H1K project cost $10 million, far more than the $50,000 threshold, the U of U should have conducted a competitive procurement process. The University believes it did not need to conduct a competitive procurement because it was an allowable exception to the competitive process. However, after consulting with the Office of Legislative Research and General Counsel and the director of Utah Purchasing and General Services, we do not believe the process met the sole source requirements found in ***Utah Code***.

Utah Code and other governing documents allowed the University to award a contract to a service provider if the use of that specific service provider is "*a condition of a donation* that will fund the full cost of the … service." The H1K gift agreement, however, did not specify a service provider. The donor's request to use his company's services was made six weeks after the gift agreement was signed. Because the gift agreement legally bound the donor to giving the University the $12 million, but specified no service provider, the sole source exception to the competitive process could not be a condition of giving those funds. In fact, the University received the first of four $3 million payments on October 2, 2014, three weeks before the donor's request. Because the request to use his company was not, therefore, a *condition* of the donation, it did not meet the exception requirements of state code.

Public Scrutiny Regarding the Validity of the Process Led to This Audit. Had the University appropriately followed state procurement requirements, state and national public scrutiny could have been avoided or mitigated. The public scrutiny surrounding the H1K

project led to this audit. The public attention also necessitated that this audit examine the process strictly according to procurement code and administrative rule.

Chapter III
Competitive Bidding Could Have Increased the Number of Genomes Sequenced

Cost Comparison Shows University Paid an Excessive Amount for Sequencing. Comparable genome sequencing facilities would have charged the University substantially less than the $10,000 sample rate negotiated with the donor's company, or the $7,289 that was ultimately charged. A lower rate would have allowed University scientists to sequence and analyze many more of the reportedly tens of thousands of genomes at the U of U. These genomes cannot be sequenced unless there is funding to do so. The other requirement, that of returning the sequencing data within 7-10 days, appears to have been neither possible nor necessary for the University and should not have constrained the selection of a facility.

Cost of Sequencing Does Not Appear to Have Been Negotiated. The H1K donation was for $12 million, with $10 million going toward the cost of sequencing the genomes and the remaining $2 million funding the cost of analysis of the resulting data. The former dean of the School of Medicine and senior vice president of Health Sciences, who negotiated the gift, stated that the gift specified 1,000 samples and the donor gave $10 million, so that works out to $10,000 per sample. She also stated that the University allowed the donor to set the price because it was his business and he knew more about the cost than they did.

Chapter IV
Sequencing Resulted in Useful Scientific Data

Heritage 1K Resulted in at Least $7.6 Million in Additional Grants. University scientists have used data generated during the H1K project to obtain $7.6 million in new money and up to $43.7 million in furthered research.

H1K Sequencing Resulted in Additional Scientific Advancement. In addition to raising additional funds because of the H1K project, the University has also made significant advancements in scientific research. The University has already published five papers, three abstracts, one clinical physician report, and identified 34 gene mutations.

REPORT TO THE
UTAH LEGISLATURE

Report No. 2017-09

A Review of the Procurement Process For the U of U's Heritage 1K Project

October 2017

Audit Performed By:

Audit Manager	Kade Minchey – CIA, CFE
Audit Supervisor	Leah Blevins - CIA

Table of Contents

Chapter I
Introduction

The Heritage 1K (H1K) project was conducted at the University of Utah (University or the U of U) from 2014-16 and consisted of the sequencing of 1,372 genome samples for 1,000 individuals. This project was made possible because of a $12 million donation to the University to sequence samples from the Utah Population Database (UPDB). An audit of H1K was requested because the sequencing was done at a facility owned by the donor, which led to questions of propriety. While this audit does not examine improprieties on the part of the donor, it does raise some concerns with the lack of a competitive bidding process to award the contract and the resulting inefficient use of the donation.

An audit was requested of H1K because of concerns with the lack of competitive bidding by the U of U.

The Heritage 1K Project Was Funded With a $12 Million Donation

The UPDB is a state asset maintained by the Huntsman Cancer Institute at the University of Utah. It is a unique resource, described by the University as

> the only database of its kind in the United States and one of few such resources in the world. The central component of the UPDB is an extensive set of Utah family histories, in which family members are linked to demographic and medical information. . . . The UPDB provides access to information on more than 8 million individuals and supports over 200 research projects.

Partially because of this unique resource, the University has a wealth of DNA samples, which are useful for research because of their family historical connection to the UPDB. University scientists report that there are tens of thousands of these samples stored at the University. To be scientifically useful, DNA samples need to undergo a process known as genome sequencing.

The U of U has a wealth of DNA samples waiting to be sequenced.

Three Agreements Formed the Project

In 2014, the University and a donor opened discussions about the possibility of forming a relationship and signed a memorandum of

understanding (MOU) in June, stating that "the Parties desire to enter a relationship in order to facilitate the exploration of opportunities for joint research and business collaboration."

Donor gave $12 million to the University to sequence at least 1,000 genomes.

After some negotiation between the donor and the University, both parties signed a gift agreement in September 2014. This gift agreement stated that the donor would give the University $12 million for "whole genome, exome, RNA sequencing and analysis of approximately 1,000 individuals distributed among Utah families affected by a variety of rare and common diseases." Two million dollars of the gift would be used for analysis of data, and the remaining $10 million would pay for the actual sequencing of the genomes.

This gift agreement also set forth some specific standards that the sequencing must meet. It required the following:

- "Highest quality, research-grade sequencing available"
- 60X coverage of the samples[1]
- Data returned within 7-10 business days from receipt of the sample

The University signed a services agreement committing them to use the services of the donor's company.

According to University attorneys, the next four months were spent looking at possible sequencing facilities to carry out the requirements of the gift agreement. During the audit, we received an email sent from the donor to the University prior to the facility selection, but after the gift agreement was signed, requesting that his company be chosen to complete the project. In January 2015, the University signed a services agreement (essentially a contract for services) with the donor's sequencing facility (facility) to do the work for the H1K project, as required by the gift agreement. The project was referred to as Heritage 1K (H1K). The services agreement required that the standards set forth in the gift agreement be met by the facility.

[1] The requirement for 60X coverage essentially means the average nucleotide base will be looked at 60 times in the process of sequencing the genome. 60X was high for genome sequencing at the time, as 30X was the standard for most samples except cancer. Cancer cells require a higher coverage.

Genome Sequencing Is Important to Scientific Discovery

Using genetics to improve medical treatment of diseases requires sequencing of the genome. Genomes contain "the full complement of all genetic information within the organism."[2] This includes all of the genes, or single units of inheritance. In the context of the H1K project, genomes were sequenced to determine whether, and which, genes have mutations. A mutation is "an alteration in the chemical structure of DNA."[3] These mutations can be "silent," or not affect the functionality of the organism, or they can result in a change of a function. [4] By sequencing genomes, scientists can identify mutations that cause diseases in order to treat that specific gene mutation.

Genome sequencing looks for mutations in genes that can eventually be medically treated.

The H1K project sequenced 1,372 genomes for projects addressing reproductive, neurologic, psychiatric, cancer, and developmental issues. The results of the sequencing have led to many scientific advancements for the University that will be discussed in more depth in Chapter IV.

Audit Scope and Objectives

This audit was requested because of questions about the propriety of donated money being paid to a company owned by the donor. This audit does not examine the donor's motivations or culpability in any wrongdoing, but instead examines only the University of Utah's responsibility. The following questions will be answered in this audit:

- Was the University's selection of the sequencing facility done appropriately according to purchasing code and policy?
- Could the University have used the donation money more efficiently by using a sequencing facility that charged less?
- What were the effects of this donation?

[2] Mukherjee, Siddhartha. 2016. *The Gene: An Intimate History*. New York: Scribner. Page 499-500.

[3] Id.

[4] Id.

Chapter II
The University Did Not Follow Procurement Statute When Awarding the Genome Sequencing Contract

When awarding the Heritage 1K (H1K) contract to the company owned by the donor, the University of Utah (University or U of U) did not follow state procurement code. While the procurement code allows for some exceptions to the competitive process, including sole sourcing, the H1K project did not meet sole sourcing requirements.[5] Furthering our concerns, U of U faculty incorrectly believed they did not need to conduct a competitive procurement when using grant funds. Failure to competitively procure these services led to public scrutiny and doubts about the validity of the contract. By competitively procuring this contract, the University could have obtained a lower cost and sequenced many more genomes.[6,7]

Utah Code Requires a Competitive Procurement for Contracts Like Heritage 1K

Because the H1K project cost $10 million, far more than the $50,000 threshold, the U of U should have conducted a competitive procurement process. The University believes it did not need to conduct a competitive procurement because it was an allowable exception to the competitive process. However, after consulting with the Office of Legislative Research and General Counsel (LRGC) and the director of Utah Purchasing and General Services (State Purchasing), we do not believe the process met the sole source requirements found in ***Utah Code***.

The University inappropriately justified the lack of competitive procurement with sole source exception.

[5] State procurement code allows a number of exceptions to the competitive procurement process. These exceptions include sole source, which occurs when there is only one provider that can do the service, and requirement of a donor gift. The requirement of a donor gift is the exception that the U of U should have sought. For simplicity sake, we will refer to this as a sole source.

[6] The issue of the cost of the services will be addressed in Chapter III.

[7] Genome sequencing involves identifying mutations in genes that can cause illnesses and diseases. This process is done to find ways to treat these mutations. For more detailed information, see Chapter I.

Utah Code Requires a Competitive Procurement Process for Large Purchases

***Utah Code* requires a competitive procurement for purchases over $50,000.**

Utah Procurement Code requires that a competitive procurement process, with the accompanying notice of a procurement and bidding, occur if the cost of the procurement exceeds $50,000.[8] The anticipated cost of this procurement[9] was $10 million, far exceeding the $50,000 threshold.

Utah Code allows exceptions to the competitive procurement requirement. One such exception occurs when it is documented that the provider of the goods or services is a sole source provider. For this exception to apply, the procurement officer must determine in writing that "there is only one source for the procurement item."[10] The sole source exception did not exist in this case because there were other providers who could perform the same services, as will be addressed in Chapter III. LRGC agrees, stating that

> [t]he basis of the University's sole source determination is not that the Company was the only source for the procurement item but that the Company was the preferable source. … Determining that the Company is the recommended source is not the same as determining that the Company is the *only* source.[11]

As such, it was incorrect to allow this sole source determination.

Exceptions can be made for a competitive procurement when the donor requests a specific provider as a condition of a donation that funds the entire cost of a project. This specific request was approved in error.

At the time the contract was awarded, ***Utah Code*** also allowed an exception to the competitive procurement requirement if

> the award to a specific supplier, service provider, or contractor is a condition of a donation that will fund the full cost of the supply, service, or construction item.[12]

It was under this allowance that the University approved the donor's request to use his company's services, and referred to this as a sole

[8] ***Utah Code*** 63G-6a-802(3)(a).

[9] A "procurement item" is defined in ***Utah Code*** as "a supply, a service, or construction."

[10] ***Utah Code*** 63G-6a-802(1)(a).

[11] A copy of LRGC's complete opinion can be found in Appendix A.

[12] ***Utah Code*** 63G-6a-802(2)(b).

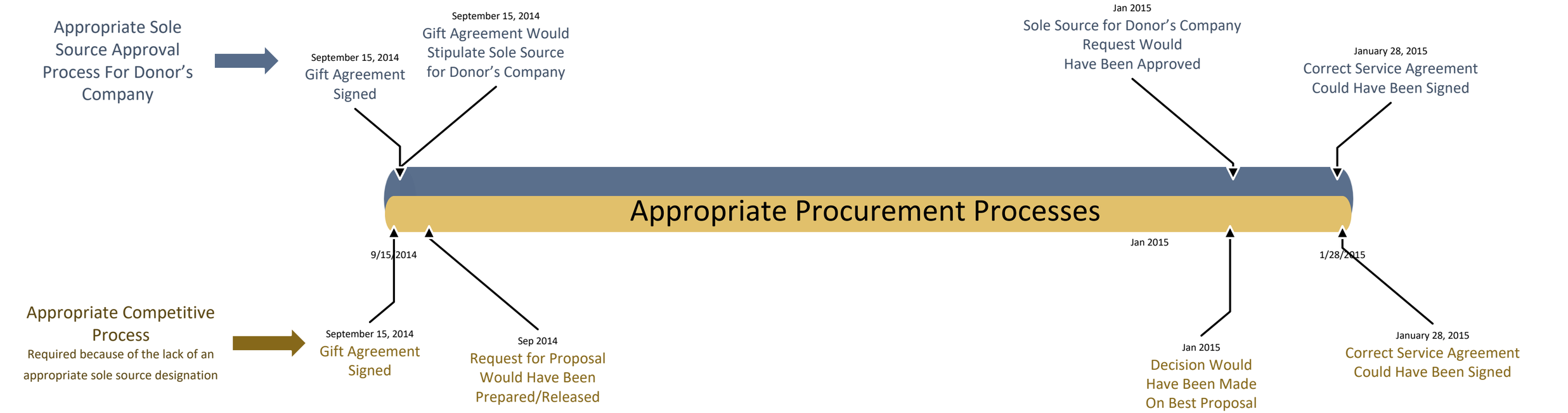
source contract. As we will discuss in the next section, this request was approved in error.

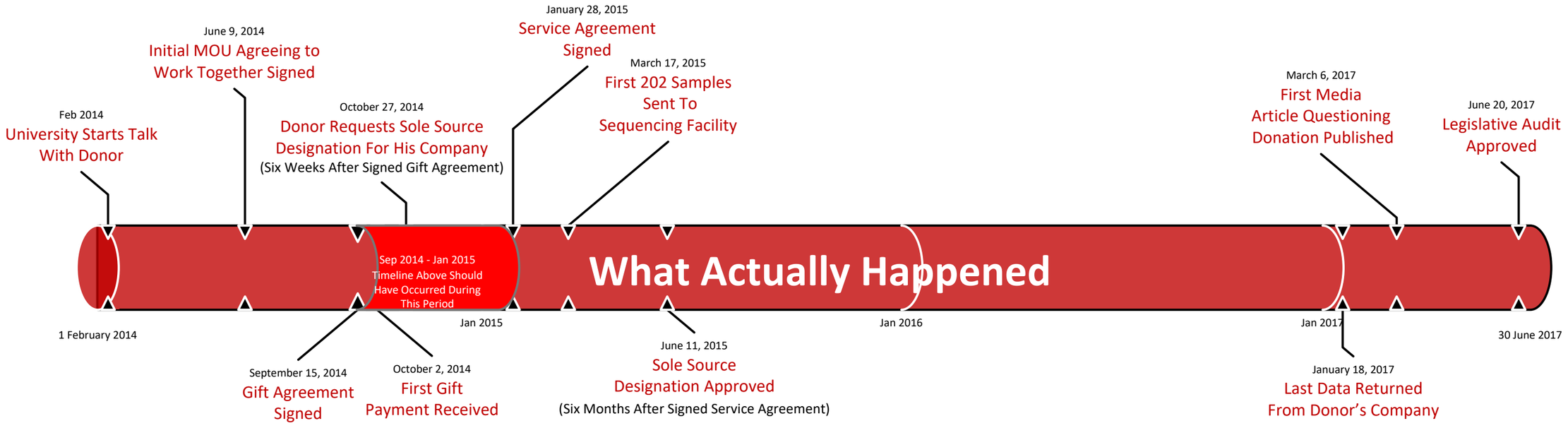
Sole Source Request Should Have Been Required in Gift Agreement

Because the donor requested his company perform the genome sequencing six weeks after the gift agreement was signed, it should not have been approved and a competitive procurement process should have been initiated. As discussed in Chapter I, the legal portion of the donation was based on three documents: the initial memorandum of understanding (MOU) stating the parties wanted to work together; the gift agreement committing the donor to giving the University $12 million; and the services agreement, which acted as a contract committing the University to pay the donor's company $10 million for genome sequencing services.

Figure 2.1 shows a timeline of the events of the donation and subsequent use of the donor's company.

Figure 2.1 This Figure Compares the Appropriate Procurement Processes with What Occurred at the University. What should have happened for an appropriate sole source designation is shown in blue, the appropriate process for a competitive procurement if sole source designation is not approved correctly is shown in yellow, and what actually happened is shown in red.





The timing shown in Figure 2.1 is important, because while the donor requested that his company be the sole source provider of the service, this request was made six weeks after the gift agreement was signed.[13]

The request to use the donor's company for the services was made six weeks after the gift agreement was signed.

Our concerns with the awarding of the contract are three-fold:

1. The timing of the approval process did not follow procurement code requirements or good practice.

2. The University's explanation for awarding the contract to the donor's company changed through the course of the audit.

3. The approval of the sole source request was made based on incorrect information.

The Timing of the Sole Source Request and Approval Followed Neither State Code, nor Best Practices. ***Utah Code*** and other governing documents[14] at the time allowed the University to award a contract to a service provider if the use of that specific service provider is "*a condition of a donation* that will fund the full cost of the … service."[15] The H1K gift agreement, however, did not specify a service provider. As shown in Figure 2.1, the donor's request to use his company's services was made six weeks after the gift agreement was signed. Because the gift agreement legally bound the donor to give the University the $12 million, but specified no service provider, the sole source exception to the competitive process could not be a condition of giving those funds. In fact, the University received the first of four $3 million payments on October 2, 2014, three weeks before the donor's request. Because the request to use his company was not, therefore, a *condition* of the donation, it did not meet the exception requirements of state code.

In order to be a condition of a gift, the requirement must be made as a condition of the gift agreement.

LRGC concurs with this opinion, stating

> [i]t is my opinion that awarding the contract to the Company without a competitive process based on the condition of donation exception was not consistent with

[13] The timing of this request will be discussed in more detail below.

[14] These include ***Utah Code*** 63G-6a-802(2)(b), Utah Board of Regent Rule, and University of Utah Rule.

[15] ***Utah Code*** 63G-6a-802(2)(b) Emphasis added.

> the Procurement Code. … I have not been made aware of anything that provides factual support for the statement that awarding the contract to the Company was a condition of the donation.

The sole source request was approved four and a half months after the services agreement was signed.

In addition, the sole source request was not approved until after the contract was signed and work had begun. After the donor made his sole source request in October, the services agreement, or contract, committing the University to pay the donor's company for the sequencing services was not signed until the following January. University Purchasing approved the sole source request four and a half months later in June. The first samples were sent for sequencing three months before the sole source request was officially approved. Both LRGC attorneys and the director of State Purchasing told us that while ***Utah Code*** does not explicitly require that sole source approval be made before the awarding of the contract, this approval should have been made before services were rendered, and certainly before the contract was signed. Otherwise, it bypasses the procurement process, whether sole source or not, which exists to ensure proper standards are in place to govern the work performed.

The University's Explanation for Awarding the Contract Changed Throughout the Audit. In our initial conversations with University attorneys involved with establishing the donation specifications, they explained that donors can specify a business to which the service should be given if the donor is funding the full cost of the project. They also told us that the University was uncomfortable with this option, and so did not allow it in this instance. Later in the process of the audit, we were shown an email requesting sole source designation and the approval memo from University Purchasing staff approving the sole source designation for the very reasons we were initially told the University was uncomfortable.

Initially we were told the University was uncomfortable with the sole source exception that was eventually approved.

The Basis for Approving the Exception to the Competitive Process Was Faulty. Finally, the memorandum recommending sole source designation for the donor's company (signed in June 2015) falsely stated that

> [t]he Gift Agreement also stipulates that the donor can recommend the facility as a sole source for the Heritage 1K sequencing…Per the email from the donor, [donor's company] is the recommended sole source provider for

these genome services. Based on this information, I recommend the sole source approval of this order.

The then-director of University Purchasing approved the request based on this recommendation. However, the gift agreement never stipulated that the donor could recommend the facility to be used. In fact, it never mentioned that the facility do the work at all. Therefore, the approval of the sole source request was based on faulty information.

The approval of the sole source request was made based on erroneous information.

The University was incorrect in concluding they did not need a competitive procurement process for the use of these donated funds. Had the donor specified in the gift agreement that his company was to be used for the genome sequencing, the sole source designation would have followed state code. In fact, LRGC stated, "[i]t appears that the University did not follow applicable requirements of the Procurement Code in entering into the contract with the Company." The University did not follow state code in this process.

U of U Staff Incorrectly Believed An RFP Was Not Required

When discussing the process for awarding the contract to the donor's company, the lead scientist for the H1K project told us the University did not typically use a competitive procurement process to choose a sequencing facility. They usually evaluate price, quality, and availability, but do not go through a competitive bid process. In his mind, this is the process that was used for the H1K project. He correctly pointed out that the services agreement has clauses that allowed either party to back out if they were dissatisfied. While we did not audit other contracts, we are concerned that the belief that competitive procurement was not required with H1K money may have led to similar errors in other grant contracts.

University staff believed they did not need a competitive procurement.

A 2016 audit conducted by our office[16] points out that received grant money is subject to procurement code requirements and recommends that "…universities should reassess their grant procurement processes to ensure they comply with statute." We

[16] Report Number ILR 2016-G "A Survey of Allegations Involving Utah State University's Anthropology Program."

concur with this recommendation and advise the University to ensure grant money is appropriately spent by conducting a competitive procurement process and providing procurement training to their staff.

Public Scrutiny Regarding the Validity of the Process Led to This Audit

Had the University followed procurement requirements, public scrutiny could have been avoided.

Had the University appropriately followed state procurement requirements, state and national public scrutiny could have been avoided or mitigated. The public scrutiny surrounding the H1K project led to this audit. The public attention also necessitated that this audit examine the process strictly according to procurement code and administrative rule. By following procurement requirements, the University could have sequenced many more genomes (which is the topic of Chapter III).

At least 11 news articles have been published questioning the validity of this process.

As shown in Figure 2.1, the H1K project was completed, with all submitted genomes sequenced and the resulting data returned to the University by January 2017. On March 6, 2017, the first article in a national publication appeared, questioning both the validity of the donation and the University of Utah's role in this process. Accusations were made that the donation was a way for the donor to funnel money to his company. One article accused the University of essentially laundering funds for the donor's company. We collected 11 national and state articles questioning the validity of this process.

A purpose of state procurement is "to ensure fair and equitable treatment of all persons…"

While the scope of this audit did not include any analysis of the donor's motivation or results for his business, we would note that by following procurement requirements and code, the University could have avoided being drawn into public scrutiny. One purpose of state and public procurement code is "to ensure the fair and equitable treatment of all persons who deal with the procurement system."[17] In our opinion, following this process presents public procurement in Utah as fair and above question. By following the prescribed process with the H1K project, the University could have shown itself to be above question. The public questions about the validity of this process

[17] ***Utah Code*** 63G-6a-102(2)

require our audit process to follow the strict letter of the law, and we find that the University did not do the same.

Recommendations

1. We recommend that the University of Utah follow procurement code and require a competitive bidding process for large bids when using grant money.

2. We recommend that the University of Utah require that exceptions to the competitive process, such as sole source designation, or requirements of donor gifts be requested at the time of the gift agreement.

3. We recommend that the University of Utah train faculty on the requirements for a competitive bid.

Chapter III
Competitive Bidding Could Have Increased the Number of Genomes Sequenced

Had the University of Utah (University, or U of U) conducted a competitive procurement process as required, it could have obtained a far lower price than the negotiated $10,000 per sample.[18] In addition, it appears that the speedy turn-around time required by the gift and services agreements may not have been attainable by any company, including the donors; therefore, the inclusion of such a restrictive time frame is questionable and should not have constrained the selection of a sequencing facility. Further, it does not appear that the University negotiated to arrive at the price charged by the donor's company, instead accepting the price set by the company.

The University should have either encouraged the donor to request sole source designation as a condition of the donation, conducted a competitive procurement with a reasonable time frame, or refused the donation. By doing none of these things, the U of U allowed the donor's specifications to steer the contract to his company, which we believe is a violation of Utah Administrative Code.[19]

[18] $10,000 per genome sequenced was the price negotiated between the University and the donor's company. Ultimately, instead of sending 1,000 samples, the University sent 1,372 samples, representing 1,000 individuals. Because the donor's company still charged the original $10 million, this means the University paid only $7,289 per genome sequenced. While we will note this when appropriate, the majority of the chapter will still refer to a price of $10,000 per sample as that is the price that would have been used in a competitive procurement.

[19] This opinion is supported by attorneys at the Office of Legislative Research and General Counsel (LRGC) found in Appendix A.

Cost Comparison Shows University Paid an Excessive Amount for Sequencing

The University could have sequenced the genomes for substantially less that what was charged by the donor's company.

Comparable genome sequencing facilities would have charged the University substantially less than either the $10,000 sample rate negotiated with the donor's company, or the $7,289 that was eventually charged. A lower rate would have allowed University scientists to sequence and analyze many more of the reportedly tens of thousands of genomes at the U of U. These genomes cannot be sequenced unless there is funding to do so. The other requirement, that of returning the sequencing data within 7-10 days, appears to have been neither possible nor necessary for the University and should not have constrained the selection of a facility.

Comparison Entities Charge Less

All three comparable entities would have charged less for sequencing services.

To determine whether the $10,000 rate the U of U negotiated for genome sequencing was competitive, we contacted six genome sequencing centers. Only three centers responded, and each reported that their expense would have been markedly lower than that charged by the donor's company. Figure 3.1 shows the cost for 60X genome sequencing, which is required by the gift agreement.

Figure 3.1 Responding Sequencing Facilities Charged Substantially Less Than the Rate of the Donor's Company. One offered a price that was one-third of the price negotiated with the donor's company.

Facility	60X Cost
Donor's Company	$10,000*
Facility 1	2,900
Facility 2[20]	4,950
Facility 3	5,000
Facility 4	Did not have capability at that time
Facility 5	Did not respond
Facility 6	Did not respond

Source: Auditor calls and compilation as verified by Dr. Richard Wilson.
** While this was the expected price as negotiated in the services agreement, the actual price eventually charged by the donor's company ended up being $7,289.*

[20] This facility is the sequencing core at Huntsman Cancer Institute. Although they report the capacity that existed at the time could not have completed in the year listed in the contract, they could have either purchased another machine for $6-700,000, or completed it in two years. From the time the first samples were submitted to the time the last data was downloaded was 22 months.

The three facilities that responded with data would have charged the University substantially less for the sequencing than the price negotiated with the donor's company.[21] Using one of these facilities would have allowed the University to sequence many more genomes. We have been told that the University has tens of thousands of samples waiting on funds that would enable them to be sequenced. This would have allowed many of these additional samples to be sequenced.

The University could have sequenced many more genome samples.

We would like to note that when determining the methodology to ensure that we were making accurate cost comparisons, we consulted with a number of experts in the field, including Dr. Richard Wilson.[22] We contracted with Dr. Wilson to review our methodology as well as our results to ensure their comparability. Dr. Wilson was of great help in forming the methodology, and along with another expert, agreed with our results, stating

Our consultant approved our methodology and our results.

> In my professional opinion, the results of this audit are scientifically and technically sound.

His letter to that effect, also listing additional concerns, is found in Appendix B.

Quick Processing Times Were Neither Necessary nor Possible

Both the gift and services agreements have two references to returning sequencing data to the University within 7-10 days. The two references are different and, in fact, conflict with one another. The two references were likely errors in drafting the agreements. This report will refer to these references as Requirement One and Requirement Two. Requirement One contains the terms that the parties followed,

The services agreement had conflicting requirements for time of return.

[21] This is despite a note in the service agreement that states, "Facility will provide the . . . Analysis to University *at a discounted cost* of $10,000 per sample or individual" (emphasis added).

[22] Dr. Wilson was recommended to us by the National Human Genome Research Institute. He holds a Ph.D. in chemistry and biochemistry from the University of Oklahoma, is a member of the International Cancer Genomics Consortium, a former co-chair of the executive committee for The Cancer Genome Atlas of the National Cancer Institute, and remains a member of that body's steering committee.

while Requirement Two was overly restrictive and was not followed by the donor's company or the University.

- Requirement One – In this timeline scenario, the University delivers a batch of samples to the donor's company, at which time they are put in the queue to be sequenced. As soon as the samples begin the actual sequencing process on the machine, the countdown begins. Within 7-10 days, the donor's company is required to make available the raw, unanalyzed resulting data.

- Requirement Two – In this timeline scenario, the University delivers a batch of samples to the donor's company, at which time the countdown begins. Within 7-10 days, the donor's company is required to make available a refined, analyzed copy of the resulting data.

By all accounts, Requirement Two would be very difficult, if not impossible, to achieve.[23] The U of U reports that the sequencing machine itself takes at least seven days to produce the raw data, which would then need to undergo analysis to produce the refined report. Requirement One, which is the requirement the University expected, is more in-line with the time lines provided by comparison entities. Figure 3.2 lists the speed at which the entities that responded said they guaranteed delivery at the time of the contract negotiation.

Figure 3.2 Comparable Sequencing Entities Would Have Taken Similar Times as the Donor's Company. These responses were from time of receipt of sample to returning raw data.

Facility	Time to Sequence (Per Sample)
Facility 1	2 weeks
Facility 2	2-4 weeks
Facility 3	6-8 weeks

Source: Auditor calls and compilation

Comparable facilities could have met the more reasonable time frame.

While none of these times would have met the time frame of Requirement Two, we believe the first two are well within the time

[23] University attorneys, other comparable sequencing facilities, and our consultant told us this is likely an impossible expectation.

frame of Requirement One, which was the actual expectation of the University and the donor's company.

U of U officials reported that they did not closely track to see whether data was received within that time frame, because they were not in a rush. In fact, the final samples were sent to the sequencer on November 18th, 2016, and the University did not download the data from those samples until January 18th, 2017. This is despite reports early in the audit that the time frame for receiving the data was a big part of the reason the donor's company was chosen.

The U of U provided no justification for the excessive speed requirement.

We have not received any evidence showing a need for expedited testing, and in fact we were told multiple times through the course of the audit that the University was not in a rush. It appears that the time frame for receiving the services was not a pressing concern for the University, but it was required by the donor in the gift agreement. The inclusion of Requirement Two appears questionable and made it difficult for the U of U to obtain less-expensive sequencing services.

Administrative Code prohibits steering a contract to a favored vendor.

The Rapid Time Frame Could Have Potentially Violated State Rule. Had a competitive procurement process been followed, Requirement Two (return of refined data in 7-10 days after delivery of the sample) may have violated the portion of Utah Administrative Code that prohibits "steering a contract to a favored vendor." This is defined as

> a person involved in the procurement process, including any phase of the procurement process, who inappropriately acts with bias or prejudice in violation of the law to favor one vendor over another vendor(s) in awarding a government contract [and includes] writing specifications that are overly restrictive, beyond the reasonable needs of the procurement unit, or in a way that gives an unfair advantage to a particular vendor without proper justification.[24]

This is especially alarming because it appears that Requirement Two was very difficult, if not impossible, for any entity, and it was never intended to be achieved. It is possible this was a drafting error on the part of the University's or donor's attorneys instead of an attempt to

[24] Utah Administrative Code R33-1-1(26)(v).

intentionally steer the contract. However, it appears the requirement may have been "beyond the reasonable needs of the procurement unit," which could be seen as steering the contract, thus violating Utah administrative code.

Cost of Sequencing Does Not Appear to Have Been Negotiated

The University stated that they allowed the donor to set the price for their services.

The Heritage 1K (H1K) donation was for $12 million, with $10 million going toward the cost of sequencing the genomes and the remaining $2 million funding the cost of analysis of the resulting data. The former dean of the School of Medicine and senior vice president of Health Sciences, who negotiated the gift, stated that the gift specified 1,000 samples and the donor gave $10 million, so that works out to $10,000 per sample. She also stated that the University allowed the donor to set the price because it was his business and he knew more about the cost than they did.

This series of points leads us to believe that the price was never negotiated or controlled by the University but was accepted as a given. Again, had procurement code been followed as discussed in Chapter II, this may not have been a problem. Utah administrative code allows a price analysis "to determine if a price is reasonable and competitive…when awarding a sole source … without engaging in a standard procurement process."[25] Because the sole source designation was not done correctly, the price should have been negotiated through the competitive procurement process. As shown above, this could have resulted in a lower price, and many additional genomes could have been sequenced.

The University could have leveraged this gift to achieve additional scientific discovery.

In conclusion, the information in this chapter shows that it was possible for the U of U to leverage this donation more effectively and sequence many more genomes. As will be discussed in the next chapter, scientific breakthroughs and additional funding resulted from the H1K donation. Had the money been used more effectively, these positive results could have multiplied.

[25] Utah Administrative Rule R33-12-603(1).

Recommendations for this chapter mirror those presented in Chapter II. Specifically, we recommend the University exercise more care in following procurement code.

Chapter IV
Sequencing Resulted in Useful Scientific Data

The Heritage 1K donation (H1K) to the University of Utah (the University) has led to both additional grant money ($7.6 million in new money and up to $43.7 million in furthered research) and valuable scientific discovery. While we are concerned with the lack of a required competitive procurement process to award the contract and the resulting inefficient use of the donation (see Chapters II and III), we acknowledge that the H1K project has benefited the University's pursuits of scientific discovery.

Heritage 1K Resulted in at Least $7.6 Million in Additional Grants

University scientists have used data generated during the H1K project to obtain addition grants to further research in their fields of study. Figure 4.1 shows the three types of grants that were possibly impacted by the H1K donation.

H1K data has been used to receive $7.6 million in additional grants, contribute to research on an additional $24.6 million, and apply for an additional $11.5 million in grants.

Figure 4.1 H1K Led to $7.6 Million in Additional Research Funds. The donation impacted research using $43.7 million in total funds.

Type of Money	Description	Amount ($ Millions)
Newly Funded Grants	Awarded based on H1K pilot data	$7.6
Existing Grants	Grants awarded before H1K, but which have used H1K as research support	24.6
Submitted Grants	Grants applied for but not yet awarded	11.5
Total	**Money Using H1K**	**$ 43.7**

Source: University of Utah Department of Human Genetics
Information as of September 5, 2017

While the bulk of this money ($24.6 million) was being used on projects funded before the H1K project, the findings of the H1K sequencing allowed the scientists to augment what they could achieve on their existing project. University officials are optimistic that many

of the grants in the "submitted" category will be funded in the near future.

Most of these grants were awarded from national institutes, including the following:

- National Cancer Institute
- National Institute of Arthritis and Musculoskeletal and Skin Diseases
- National Institute of Neurological Disorders and Stroke
- Eunice Kennedy Shriver National Institute of Child Health and Human Development

Other grant monies were awarded from the George S. and Dolores Doré Eccles Foundation and others.

H1K Sequencing Resulted in Additional Scientific Advancement

Numerous publications and gene identifications resulted from the H1K information.

In addition to raising additional funds because of the H1K project, the University has also made significant advancements in scientific research. Figure 4.2 lists the scientific and academic advancements the University has achieved in correlation with H1K.

Figure 4.2 The University Has Identified New Gene Mutations, Published Papers, and Presented Abstracts as a Result of H1K. These advancements have been made in many areas of study.

Advancement	Number
Publications	5
Abstracts	3
Identified Gene Mutations	34
Clinical Physician Reports	1

Source: University of Utah Department of Human Genetics
Information as of September 5, 2017

Publications are articles written by scientists and published in academic journals. Abstracts are brief descriptions of presentations given at major meetings. Publications and abstracts are the "coin of the realm" for science. They are reviewed by several peers before being accepted to a journal, a process that helps ensure that the findings are valid. If research is not published and disseminated to scientific colleagues, it has limited value.

As discussed in Chapter I, the identification of gene mutations is important in scientific and health care discovery. A mutation is "an alteration in the chemical structure of DNA."[26] These mutations can be "silent," having no effect on the functionality of an organism, or they can result in a change of a function.[27] In the H1K project, scientists are trying to identify mutations that either cause diseases or bring about positive outcome. If a mutation causes disease, scientists will look for a way to treat that mutation. If it generates positive results, they will try to determine how the mutation could benefit others. Projects studied with H1K money include, but are not limited to the following:

The H1K project researched a broad range of subjects, including cancers, mental illnesses, and other diseases.

- Longevity
- High altitude adaptation
- Spontaneous preterm birth
- Other reproductive conditions
- Neurological conditions
- Suicide
- Autism
- Metabolic conditions
- Arthritis
- Developmental conditions
- Vascular conditions
- Pediatric common variable immune disease
- Cancer syndromes
- Solid tumors
- Hematologic tumors
- Undiagnosed diseases

Further study into these conditions could lead to great improvements in all of these health areas, which span much of the human condition. Although we expressed concerns with efficient use of the H1K donation, the project has undoubtedly led to valuable scientific progress. Despite our concerns, on the whole, the H1K donation and project has been a boon in the University's quest for scientific discovery.

[26] Mukherjee, Siddhartha. 2016. *The Gene: An Intimate History*. New York: Scribner. Page 499-500.

[27] Id.

Appendices

Appendix A
Letter from LRGC Attorneys

OLRGC
Office of Legislative Research and General Counsel

John Q. Cannon
Director

John L. Fellows
General Counsel

September 29, 2017

Leah Blevins
Senior Audit Supervisor
Office of the Legislative Auditor General
Utah State Capitol Complex, Suite W315
Salt Lake City, Utah 84114

Subject: University of Utah audit

Dear Leah,

You have asked my opinion concerning a legal issue that has arisen in the context of your audit of the University of Utah ("University") relating to a contract between the University and a company ("Company") providing whole genome sequencing and other services. Specifically, you asked whether the process the University used to procure the contract with the Company complied with applicable provisions of Title 63G, Chapter 6a, Utah Procurement Code ("Procurement Code").[1]

Short Answer

It appears that the University did not follow applicable requirements of the Procurement Code in entering into the contract with the Company.

Discussion

General Applicability of the Procurement Code

The Procurement Code applies "to every expenditure of public funds irrespective of the source of the funds, . . . by any procurement unit under any contract."[2] The University is a "procurement unit"[3] and is therefore subject to the Procurement Code.[4] The University's expenditure of funds to acquire the services provided under the contract with the Company is subject to the requirements of the Procurement Code.

---

[1] All references to the Utah Code are to the 2014 version of the Utah Code in effect during 2014 and early 2015 when the relevant events took place.

[2] Utah Code Section 63G-6a-105(2)(a).

[3] As an institution of higher education, the University is an "educational procurement unit," as defined in Section 63G-6a-104(7), which is one type of "procurement unit," as defined in Section 63G-6a-104(14).

[4] More specifically, the University is a "procurement unit with independent procurement authority." As a procurement unit with independent procurement authority, the University is required to "comply with the requirements of" the Procurement Code. Utah Code Section 63G-6a-106(4)(c).

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The University's Compliance with the Procurement Code

Ordinarily, the Procurement Code requires a procurement unit to use a competitive process when selecting a vendor to provide a good or service that the procurement unit wants to acquire. However, the Procurement Code in effect at the time of the initiation of the contract provides for some exceptions to the competitive process requirement. As relevant here, the Procurement Code[5] states that a procurement unit may award a contract without competition if:

- "there is only one source for the procurement item" ("sole source exception"); or
- "the award to a specific supplier, service provider, or contractor is a condition of a donation that will fund the full cost of the supply, service, or construction item" ("condition of donation exception").

The University appears to rely on one or both of these exceptions to support its selection of the Company without the use of a competitive process. Based on the information I have received about the selection of the Company, it is my opinion that neither exception applies.

Sole source exception

A procurement unit may award a contract without competition if it "determines in writing that . . . there is only source for the procurement item."[6] Over four months after entering into a contract with the Company, the University recommended in writing that the Company be given "sole source approval."[7] Although the June memo arguably qualifies as the required written determination, it is my opinion that awarding the contract to the Company without a competitive process based on the sole source exception was not consistent with the Procurement Code.

The basis of the University's sole source determination is not that the Company was the only source for the procurement item but that the Company was the preferable source. Had the University determined that the Company was the preferable source following the use of a competitive process, the selection of the Company would have been defensible. However, the University determined that the Company was the preferable source without having used a competitive process.

The University's written sole source determination – the June memo -- is based on an email from a principal of the Company to a University purchasing official, requesting that the

[5] Utah Code Section 63G-6a-802(2).

[6] Utah Code Section 63G-6a-802(2).

[7] That recommendation is contained in a memorandum dated June 11, 2015 from the University purchasing department ("the June memo"). Although the Procurement Code does not explicitly require the written determination to be made before the sole source contract is entered into, it is difficult to see how a procurement unit could justify not using a competitive process based on there being only one source for the procurement item when the determination that there is only one source does not occur until after the provider is selected and the contract executed.

Company be "the sole source sequencing provider for Heritage 1K Project." The principal's email states that the Company is "uniquely capable," that the Company would "work collaboratively with Heritage 1K scientists to maximize the useful information obtained from each sample and project," and that the Company would provide "a superior level of service." The June memo relies on the principal's email to determine that the Company "is the recommended sole source provider for these genome services."

Determining that the Company is the recommended source is not the same as determining that the Company is the *only* source. While the advantages described in the Company principal's email may be true, those advantages do not provide a proper basis for determining that the Company is the only source for the procurement item. Determining that a particular provider offers the greatest advantages to the procurement unit is the purpose and function of the competitive process, where multiple potential providers are given the opportunity to compete and demonstrate why their proposal offers the best value to the procurement unit. Declaring that an individual provider offers the most advantages without going through a competitive process does not provide a proper basis for determining that the provider is the only source of the procurement item and is not a proper application of the sole source exception.

Finally, it appears that any determination that there was only one source for the procurement item that the University sought to acquire would have been factually incorrect. You have informed me that there are multiple companies that could potentially have provided the procurement item according to the specifications required by the University.

Condition of Donation Exception

A procurement unit may award a contract without competition if it "determines in writing that . . . the award to a specific supplier, service provider, or contractor is a condition of a donation that will fund the full cost of the" procurement item.[8] It is my opinion that awarding the contract to the Company without a competitive process based on the condition of donation exception was not consistent with the Procurement Code.

The University received a $12 million donation that was memorialized in a gift agreement dated September 15, 2014. The purpose of the donation was to provide funding for a "whole genome, exome, RNA sequencing and analysis" project. It is my understanding that the money from this gift was intended to fund the work that became the subject of the contract between the University and the Company.

To award a contract without competition in reliance on the condition of donation exception, a procurement unit is required to make a written determination that the award to a specific provider is "a condition of a donation that will fund the full cost of the" contract. Arguably the June memo fulfilled the requirement for a written determination. The June memo states that

[8] Utah Code Section 63G-6a-802(2).

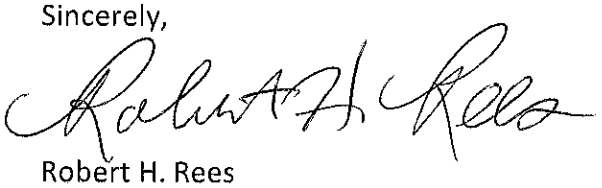
the September 15, 2014 gift agreement "stipulates that the donor can recommend the facility as a sole source for the Heritage 1K sequencing."

Despite that determination, I have not been made aware of anything that provides factual support for the statement that awarding the contract to the Company was a condition of the donation. The gift agreement states that it "constitutes the entire agreement between the parties" and "may not be modified except by written instrument executed by both parties." However, there is nothing in the agreement directing the University to award the contract to the Company, and I have not been made aware of any other written instrument that contains that direction.

It appears that awarding the contract to the Company was not a condition of the $12 million donation to the University. The University's failure to use a competitive process to award the contract to the Company is not supported by the condition of donation exception of the Procurement Code.

If you have any questions about this letter, please feel free to contact me.

Sincerely,



Robert H. Rees
Associate General Counsel

Appendix B
Letter from Dr. Richard Wilson, Scientific Consultant

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

Institute for Genomic Medicine

October 1, 2017

To whom it may concern:

I am a molecular biologist and geneticist with specific expertise in large-scale genome sequencing and analysis. I have worked in this field for over 30 years and have made substantial contributions, particularly in the areas of technology and methods implementation, cancer genomics, and personalized medicine. My laboratory at Washington University in St. Louis was the first to sequence the complete genome of a multicellular organism (the roundworm *C. elegans*, in 1998), the first to sequence the genome of a cancer patient (in 2008), and contributed substantially to the sequencing of the human genome (from 1990-2003). To date I have published 389 peer-reviewed articles in major scientific journals with an impact factor that ranks in the top 1% of persons working in my field. In 2011, I was honored by election as a Fellow to the American Association for the Advancement of Science (AAAS). At present, I am the Executive Director of the Institute for Genomic Medicine at Nationwide Children's Hospital in Columbus, Ohio, and a Professor of Pediatrics at The Ohio State University College of Medicine.

I have worked with auditors from the Office of the Legislative Auditor General to ensure that discussions and methodology of the science behind genome sequencing is appropriate and accurate. I have reviewed:

- The language in the report for scientific and industry accuracy.
- Methodology in the cost comparison to ensure comparisons are reasonable.
- Results of the cost comparison to ensure they were analyzed correctly.
- The contracts and legal documents to determine whether they are in line with industry standards.

I was also able to guide the auditors to specific individuals to talk to while performing the audit, and offer my professional opinion on areas of concern.

In my professional opinion, the results of this audit are scientifically and technically sound. Specifically,

- The comparison of costs between genome sequencing facilities was done appropriately, and enables the auditors to make commensurable comparisons.
- The costs found at comparable facilities is in line with my professional experience, indicating that $10,000 per sample was an excessive price (about two-fold).
- The expectation that a sample could be delivered to a facility, sequenced, the data analyzed and refined and returned to the University in seven to ten days was highly unlikely, if not impossible at the time the work was specified and performed.
- Despite some weaknesses, the Heritage 1K donation led to valuable scientific results.

Additionally, in the process of reviewing the information in the audit, as well as the legal documentation on which the project was based, I reached the following conclusions that lead to questions about the arrangement:

- 60X sequence coverage is excessive for individual genomes unless they are derived from tumor tissue and likely to be aneuploid (i.e. contain extra chromosomes) or heterogeneous (i.e. a complex mixture of cell types). 30X coverage is sufficient, and as it is also less expensive, would have allowed the University to sequence many additional samples.
- Language in both the Gift and Services Agreements that allows facility scientists to analyze and co-publish findings is very unusual and is unlikely to have been acceptable in such agreements in my experience.
- Language in the Services Agreement conceding that intellectual property resulting from the testing is unlikely is unusual and disingenuous at best. The aim of these studies is to identify gene mutations that can lead to better diagnoses and treatments. Therefore, one would certainly have some expectation that IP would result from sequencing these valuable samples. However, I am encouraged that it was specified that the University of Utah (rather than the company) would own any resulting intellectual property.
- It appears that the Gift Agreement intentionally included specifications that could be interpreted as unique to the Donor's facility, thereby perhaps sending a message to University administrators that his was only facility that was "qualified" to do the work (i.e., "sole source"). One wonders if this, and/or some fear of offending the Donor, resulted in the decision to not work with a different facility that could have done the work at lower costs. However, in reviewing the Gift Agreement, I did not conclude that the specifications for sequencing ("Omics Analysis") were written so strictly that the University was left without some wiggle room.

In conclusion, this audit and its results are, in my professional opinion, technically and scientifically sound and accurate.

Sincerely,

Richard K. Wilson, Ph.D.
Nationwide Foundation Endowed Chair in Genomic Medicine
Executive Director, The Institute for Genomic Medicine
Professor of Pediatrics

Agency Response

HEALTH
UNIVERSITY OF UTAH

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October 6, 2017

John M. Schaff
Office of the Legislative Auditor General
W315 State Capitol Complex
Salt Lake City, Utah 84114

Re: Utah Legislative Audit Report No. 2017-09

Dear Mr. Schaff:

Thank you for the opportunity to respond to your office's Review of the Procurement Process for the U of U's Heritage 1K Project (the "Report"). The University of Utah appreciates the thoroughness and professionalism of your team in conducting the audit and the constructive recommendations of the Report. We are committed to compliance with the Utah Procurement Code and will work diligently to implement the recommendations in the Report.

The University's responses to the recommendations are attached.

Sincerely,

A. Lorris Betz, MD, PhD
Interim
CEO, University of Utah Health
Executive Dean, University of Utah School of Medicine
Senior Vice President for Health Sciences

UNIVERSITY OF UTAH RESPONSES AND PLAN TO IMPLEMENT RECOMMENDATIONS FROM THE AUDIT REPORT

The University of Utah, in conjunction with its Procurement and Contracting Services Department, Health Sciences Center, and other University administrative departments has begun the process of implementing all recommendations of the Review of the Procurement Process for the U of U's Heritage 1K Project (the "Report"). Those recommendations, and the University's actions in response, are as follows:

Chapter II The University Did Not Follow Procurement Statute When Awarding the Genome Sequencing Contract

Recommendation 1 – *We recommend that the University of Utah follow procurement code and require a competitive bidding process for large bids when using grant money.*

Response. The University accepts this recommendation and is committed to complying with the Utah Procurement Code. The University is increasing its educational efforts and programs to educate University faculty and staff, including investigators and grant administrators, regarding the procurement code and compliance requirements. These efforts include written and in person education, as well as adding specific educational modules in its research administration training series.

Recommendation 2 – *We recommend that the University of Utah require that exceptions to the competitive process, such as sole source designation, or requirements of donor gifts be requested at the time of the gift agreement.*

Response. The University accepts this recommendation and has undertaken renewed efforts to educate University faculty and staff regarding the requirements of a sole source designation, including educating administrators regarding timing on sole source requirements for donor gifts.

Recommendation 3 – *We recommend that the University of Utah train faculty on the requirements for a competitive bid.*

Response. The University accepts this recommendation and has undertaken renewed efforts to educate faculty and staff regarding the requirements of the procurement code, including the requirements for competitive bidding for the purchase of goods and services.