

**REPORT/RECOMMENDATION TO THE BOARD OF SUPERVISORS
OF SAN BERNARDINO COUNTY
AND RECORD OF ACTION**

March 28, 2023

FROM

WILLIAM L. GILBERT, Director, Arrowhead Regional Medical Center

SUBJECT

Master Agreement with Cayuse, LLC for a Cloud-Based Institutional Review Board System to Manage Research Protocol Compliance

RECOMMENDATION(S)

Approve a Master **Agreement No. 23-237** with Cayuse, LLC, including non-standard terms, for a cloud-based Institutional Review Board system, to digitally manage research protocols in compliance with federal research requirements, in the amount of \$33,825, for the retroactive period of January 1, 2023 through December 31, 2027.
(Presenter: William L. Gilbert, Director, 580-6150)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

Operate in a Fiscally-Responsible and Business-Like Manner.

Provide for the Safety, Health and Social Service Needs of County Residents.

FINANCIAL IMPACT

Approval of this item will not result in the use of Discretionary General Funding (Net County Cost). The cost of \$33,825 is funded by State Medi-Cal, Federal Medicare, private insurances, and other departmental revenue. Funding sources may change in the future pending any legislative activity related to the repeal and/or replacement of the Affordable Care Act. Adequate appropriation and revenue have been included in the Arrowhead Regional Medical Center (ARMC) 2022-23 budget and will be included in future recommended budgets.

BACKGROUND INFORMATION

This Master Agreement (Agreement) with Cayuse, LLC. (Cayuse) will continue to enable ARMC to access a cloud-based Institutional Review Board (IRB) system to digitally manage research protocol compliance in accordance with federal research requirements. As a teaching hospital, ARMC is required to establish an IRB system to ensure all research proposals meet mandated protocols. Cayuse provides a platform for ARMC to facilitate research involving human subjects that meets ethical and academic standards. Cayuse helps with the facilitation of all documentation reviews and research procedures associated with the IRB process.

On December 8, 2020, the Purchasing Agent approved Master Agreement No. 4100186520 with Saabertech for an IRB software called iMedRis. The original agreement was for three years. However, Saabertech has been acquired by Cayuse, a company that provides enterprise solutions for research and grant administration, and now requires a new Master Agreement with Cayuse.

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The item is retroactive due to the acquisition of Saabertech by Cayuse, and extensive contract negotiations between Cayuse and the County that concluded December 12, 2022. The vendor provided an additional update to the Agreement on January 27, 2023, which required review by Counsel. This item is being retroactively presented at this time as this is the first available date following the required operational, fiscal, and legal reviews.

The Agreement is Cayuse's standard commercial contract, which includes terms that differ from the standard County contract and omits certain County standard contract terms. While the parties negotiated certain contract terms to County standards, Cayuse would not agree to certain County standard terms. The non-standard and missing terms include the following:

1. The Agreement does not require Cayuse to indemnify the County, as required by County Policy 11-07, including for intellectual property infringement claims.
 - The County standard contract indemnity provision requires the contractor to indemnify, defend, and hold County harmless from third party claims arising out of the acts, errors or omissions of any person. The standard contract provision for intellectual property indemnity is: Contractor will indemnify, defend, and hold harmless County and its officers, employees, agents and volunteers, from any and all third party claims, costs (including without limitation reasonable attorneys' fees), and losses for infringement of any United States patent, copyright, trademark or trade secret (Intellectual Property Rights) by any goods or services.
 - Potential Impact: Cayuse is not required to defend, indemnify or hold the County harmless from any claims, including indemnification for claims arising from Cayuse's negligent or intentional acts and intellectual property infringement. If the County is sued for any claim, including intellectual property infringement based on its use of Cayuse's software or services, the County may be solely liable for the costs of defense and damages, which could exceed the total Agreement amount.
2. Cayuse's maximum liability to the County is limited to two times the fees paid or payable by the County to Cayuse in the 12 full calendar months immediately preceding the month in which the event giving rise to the claim occurred.
 - The County standard contract does not include a limitation of liability.
 - Potential Impact: Claims could exceed the liability cap and the Agreement amount leaving the County financially liable for the excess.
3. The County may not terminate the Agreement for convenience.
 - The County standard contract gives the County the right to terminate the contract, for any reason, with a 30 day written notice of termination without any obligation other than to pay amounts for services rendered and expenses reasonably incurred prior to the effective date of termination.
 - Potential Impact: The County can only terminate the Agreement during the term for an uncured breach by Cayuse. Any attempted termination by the County without cause would result in payment liability for the full Agreement amount, which could result in payment liability where no funds are available due to lack of allocation or loss of funding.

ARMC recommends approval of the Agreement, including non-standard terms, to maintain and monitor research protocols effectively and in accordance with federal research requirements for the safety, health and social service needs of county residents.

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PROCUREMENT

The Purchasing Department supports the non-competitive procurement based on an existing agreement and functional specifications. The agreement with Saabertech was for three years through December 2023; however, after the company was acquired by Cayuse, Board approval is needed for a new Master Agreement. Additionally, the software from Cayuse is unique because it is the only cloud-based, fully comprehensive IRB system that services more 600 research institutions globally, with enhanced security features that are critical for a teaching hospital like ARMC to ensure compliance with federal research requirements. As part of the Cayuse network, ARMC has access to the best practices of their many research partners in the United States, and around the world, to develop the most robust research program possible for the benefit of county residents.

REVIEW BY OTHERS

This item has been reviewed by County Counsel (Bonnie Uphold, Supervising Deputy County Counsel, 387-5455) on February 28, 2023; Purchasing (Ariel Gill, Buyer III, 777-0722) on February 17, 2023; Risk Management (Victor Tordesillas, 386-8623) on February 3, 2023; ARMC Finance (Chen Wu, Finance and Budget Officer, 580-3165) on March 7, 2023; Finance (Jenny Yang, Administrative Analyst, 387-4884) on March 8, 2023; and County Finance and Administration (Valerie Clay, Deputy Executive Officer, 387-5423) on March 9, 2023.

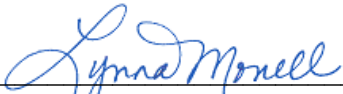
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Record of Action of the Board of Supervisors
San Bernardino County

APPROVED (CONSENT CALENDAR)

Moved: Joe Baca, Jr. Seconded: Curt Hagman
Ayes: Col. Paul Cook (Ret.), Jesse Armendarez, Dawn Rowe, Curt Hagman, Joe Baca, Jr.

Lynna Monell, CLERK OF THE BOARD

BY 
DATED: March 28, 2023



cc: ARMC- Gilbert w/agree
Contractor- C/O ARMC w/agree
File- w/agree
LA 03/31/2023