

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

August 20, 2024

FROM

ANDREW GOLDFRACH, ARMC Chief Executive Officer, Arrowhead Regional Medical Center

SUBJECT

Non-Financial Affiliation Agreement and Institutional Review Board Authorization Agreement with RAND Corporation

RECOMMENDATION(S)

1. Approve non-financial Affiliation **Agreement No. 24-777** with RAND Corporation for the provision of Research Assistants for work on the National Institutes of Health funded study, Adaptive Interventions for Emergency Department Patients with Opioid Use Disorder, effective from the date of execution through March 31, 2028.
2. Approve non-financial Institutional Review Board Authorization **Agreement No. 24-778** with RAND Corporation for the Arrowhead Regional Medical Center Institutional Review Board to rely on the RAND Corporation Institutional Review Board for the Adaptive Interventions for Emergency Department Patients with Opioid Use Disorder Study, effective from the date of execution and continuing until terminated by either party.

(Presenter: Andrew Goldfrach, ARMC Chief Executive Officer, 580-6150)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

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) as the Agreements with RAND Corporation (RAND) are non-financial in nature.

BACKGROUND INFORMATION

The Affiliation Agreement will provide Arrowhead Regional Medical Center (ARMC) with RAND research assistants and observers to work directly with ARMC personnel and hospital patients to improve effectiveness of treatment services and reduce overdose and suicide ideation under the National Institutes of Health (NIH) funded study, Adaptive Interventions for Emergency Department Patients with Opioid Use Disorder (ADAPTED).

Under federal law, clinical trials and certain research studies in healthcare facilities involving human subjects must be approved and supervised by each facility's Institutional Review Board (IRB) to ensure the protection of those subjects. However, in large scale studies, the primary facility involved in the study may serve as the central IRB to ensure that the study is conducted consistently at all study sites.

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In order to do this, and to comply with federal law, facilities involved in such studies must enter into an authorization agreement that authorizes the second study sites to rely on the central IRB for review, approval, and continuing oversight of the study in lieu of its own IRB. In an authorization agreement, the review performed by the central IRB will meet the human subject protection requirements of the local facility's Federalwide Assurance, which is the assurance of compliance with the United States federal regulations for the protection of human subjects in research. The IRB Authorization Agreement with RAND is the authorization agreement described above with respect to the ADAPTED Study and will enable RAND's IRB to serve as the central IRB for the study at ARMC.

For the past five years, ARMC has had a very successful Substance Use Navigator program in place through the Emergency Department. ARMC has received State of California funding in prior years to help facilitate this program and the success rate is one of the highest in the State. Due to the successes of ARMC's existing programs, in March 2021 RAND approached ARMC to discuss the possibility of having ARMC be the site in a NIH grant application that RAND was applying for to study the integration of mental health counseling into ARMC's existing program. RAND was subsequently awarded the grant by the NIH to conduct the ADAPTED study at ARMC.

On February 27, 2024 (Item No. 19), the Board of Supervisors approved the Revenue Subaward Agreement with RAND for ARMC to participate in the ADAPTED study in the amount of \$111,065 for the period of February 27, 2024 through March 31, 2028.

ARMC recommends approval of the Affiliation and IRB Authorization Agreements to allow the study to begin at ARMC, subject to IRB approval, for the health, safety, and social service needs of County residents.

PROCUREMENT

Not applicable.

REVIEW BY OTHERS

This item has been reviewed by County Counsel (Charles Phan, Supervising Deputy County Counsel, 387-5455) on July 24, 2024; ARMC Finance (Chen Wu, Finance and Budget Officer, 580-3165) on July 26, 2024; Finance (Jenny Yang, Administrative Analyst, 387-4884) on July 29, 2024; and County Finance and Administration (Valerie Clay, Deputy Executive Officer, 387-5423) on August 5, 2024.

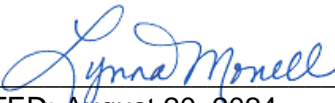
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Record of Action of the Board of Supervisors
San Bernardino County

APPROVED (CONSENT CALENDAR)

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

Lynna Monell, CLERK OF THE BOARD

BY 
DATED: August 20, 2024



cc: ARMC - Goldfrach w/agree
 Contractor - c/o ARMC w/agree
 File - w/agree
MBA 08/22/2024