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

July 14, 2020

FROM

WILLIAM L. GILBERT, Director, Arrowhead Regional Medical Center

SUBJECT

Subaward Agreements from the National Coordinating Center - University of Cincinnati

RECOMMENDATION(S)

1. Approve **Subaward Agreement No. 20-571** with the National Coordinating Center – University of Cincinnati on behalf of Beth Israel Deaconess Medical Center, Inc. for SATURN clinical trials related to the study of intracerebral hemorrhage patients, not to exceed $3,550 per participating patient at Arrowhead Regional Medical Center, for the performance period of July 14, 2020, through May 31, 2026.
2. Approve **Subaward Agreement No. 20-572** with the National Coordinating Center – University of Cincinnati on behalf of Yale University for ASPIRE clinical trials related to intracerebral hemorrhage patients, not to exceed $10,810 per participating patient at Arrowhead Regional Medical Center, for the performance period of July 14, 2020, through April 30, 2024.
3. Direct the Director of Arrowhead Regional Medical Center to transmit the agreements to the Clerk of the Board of Supervisors within 30 days of execution by the National Coordinating Center – University of Cincinnati.

(Presenter: William L. Gilbert, Director, 580-6150)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

Promote the Countywide Vision.
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 the recommendations will not result in the use of Discretionary General Funding (Net County Cost). The University of Cincinnati through the National Institutes of Health (NIH) Stroke Net does not require a match from the County to receive funding for clinical trials. If Arrowhead Regional Medical Center (ARMC) requests to hire a FTE as a result of the funding from the clinical trials, ARMC will return to the Board of Supervisors (Board) for the necessary approval and budget adjustments.

BACKGROUND INFORMATION

The NIH created the NIH Stroke Net to conduct small and large clinical trials and research studies to advance acute stroke treatment, stroke prevention, and recovery and rehabilitation following a stroke across the lifespan. Yale University was awarded the ASPIRE clinical trial and Beth Israel Deaconess Medical Center, Inc. was awarded the SATURN clinical trial. Both

institutions then contracted with the University of Cincinnati (acting as the national coordinating center) to issue subawards to other participating institutions, which would include ARMC.

The subawards from NIH Stroke Net will provide for the safety, health and social services needs of County residents through the study of the effectiveness of anti-cholesterol drugs and anti-coagulation drugs in the prevention of strokes. ARMC is a certified Stroke Center, and is also a member of the NIH Stroke Net, which enables the hospital to participate in national research studies.

Generally, enrollment in clinical trials are approved by the ARMC Internal Review Board (IRB) and do not require Board of Supervisor approval. ARMC has enrolled in 2 projects studying Intra-Cerebral Hemorrhage (ICH): (1) Statins Use in Intracerebral Hemorrhage Patient (SATURN), and (2) Anticoagulation in ICH Survivors for Prevention and Recovery (ASPIRE). In order to participate in the research projects, the ARMC Stroke Program received approval from the ARMC IRB. The enrollment requests were also approved by the Beth Israel Deaconess Medical Center, a teaching hospital of Harvard Medical School (Harvard), for the SATURN research project, and Yale University (Yale) for the ASPIRE research project.

Most clinical trials in which ARMC participates do not result in financial awards to the hospital/County. However, ARMC was presented with subaward agreements for the SATURN study not to exceed $3,550 per participating patient, and the ASPIRE study not to exceed $10,810 per patient for the duration of the clinical trials. The actual amount per patient is dependent on what stage the patient gets through in the clinical trials. Based on 2019 volume, eligible patients in the SATURN study will be approximately 110 patients per year, and eligible patients in the ASPIRE study will be approximately 10 patients per year. The patients eligible to participate in these studies are those who have suffered and survived intra-cerebral hemorrhage and are prescribed anti-cholesterol or anti-coagulation medications.

As discussed, the University of Cincinnati ("UC") is the National Coordinating Center for both studies, and is the pass-through entity for the prime recipients (Harvard and Yale), which contracts with subrecipients, such as ARMC for the subaward agreements.

The subaward agreements are the UC's standard clinical trial agreements that are required to be used for NIH subawards. The template for these agreement is prepared by the Federal Demonstration Partnership, and overall, the terms and conditions of the agreements are equitable for both parties, but they deviate from the County's standard contract terms. The non-standard terms and their potential impact are as follows:

<u>Audit</u>
The agreements require that if ARMC becomes aware of an audit or investigation by a regulatory agency with jurisdiction over the study, ARMC must provide the Medical University of South Carolina[1] ("MUSC") with prompt notice of the audit/investigation, and if permitted by the agency, ARMC must allow MUSC to be present during the audit. MUSC must be provided with a copy of any formal response by ARMC to any inquiries by any regulatory agency with jurisdiction over the studies.

- The County's standard contract does not permit the other party to be present during a government audit/investigation in relation to a particular vendor's contract.

[1] MUSC is the national data management center ("NDMC") for the two studies, where the data from ARMC relating to the studies will be submitted. MUSC supports protocol data management, ensures data quality, and undertakes interim monitoring, analyses and reporting for the UC and NIH.

- Potential Impact: This provision imposes burdens on the County that would not normally be present in the County's standard contract. ARMC's employees must be mindful of these additional obligations and comply with them to the extent the situation arises.

Insurance

The agreements require each party to maintain sufficient general and professional liability insurance/malpractice insurance or self-insurance to cover liability for their respective responsibilities, but do not require adding each other as an additional insured and or the waiver of subrogation rights.

- The County has an extensive list of insurance requirements relating to various insurance coverage and limits, and requires vendors to add the County as an insured and to waive subrogation of rights.
- Potential Impact: The agreements are silent on any limits of insurance. This means the County has no assurance that UC will have sufficient insurance to cover any claims that may arise, which could result in the County bearing financial responsibility if UC's insurance coverages are insufficient to meet its liability. Additionally, UC's insurance policy will not provide direct coverage to the County as a named insured. Lastly, without a waiver of subrogation, UC's insurers may bring suit against the County.

Indemnification

The agreements are silent on any indemnification obligations.

- The standard contract provision for indemnification requires the vendor to defend, indemnify, and hold the County harmless from any claims of intellectual property infringement and third-party claims arising out of the acts, errors or omissions of any person.
- Potential Impact: UC is not contractually required to defend, indemnify, and hold the County harmless from any claims whatsoever. If the County is sued for any claim, including intellectual property infringement based on its activities under the agreements, the County may be solely liable for the costs of defense and damages, which could exceed the total contract amount. It should be noted, however, that the County may potentially be able to pursue an implied indemnity claim even though the contract does not contain an express indemnification provision.

Warranty

Under the agreements, neither party makes any warranty, express or implied, including any implied warranty of merchantability or fitness for a particular purpose with respect to any research activity or article supplied by it or to its principal investigator, nor with respect to any patent, trademark, know-how tangible research property, information or data provided to the other party, and each party disclaims the same.

- The County standard contract provides that the other party fully warrants its services and products.
- Potential Impact: UC's liability is limited by this disclaimer of warranty. ARMC must be mindful and use appropriate professional judgment when making decisions in complying with the protocol for the two studies.

Though the agreements identify the subaward estimated project period as starting on September 1, 2019 for the SATURN study and July 1, 2019 for the ASPIRE study, these start dates reflect the subawardee start dates of these particular studies generally, and not the actual

start date of ARMC's involvement with the studies. ARMC will start obtaining funding relating to these studies upon execution of the subaward agreements by the parties.

ARMC recommends approval of the subaward agreements, including the nonstandard terms, to support and enhance the work of ARMC's Stroke Program. The hospital's initial plan for the use of these funds is to hire a Staff Analyst who will track and process funding received from the studies, conduct data entry and follow up with patients, in addition to supporting activities for the Stroke and Cardiac Programs. If adequate funds are received, the funds would also be used for the purchase of equipment, community education, stroke research, and community stroke events.

PROCUREMENT
Not applicable.

REVIEW BY OTHERS
This item has been reviewed by County Counsel (Charles Phan, Deputy County Counsel, 387-5289) on June 12, 2020; ARMC Finance (Chen Wu, Finance and Budget Officer, 580-3165) on June 17, 2020; Finance (Yael Verduzco, Administrative Analyst, 387-5285) on June 23, 2020; and County Finance (Matthew Erickson, County Chief Financial Officer, 387-5423) on June 28, 2020.

Record of Action of the Board of Supervisors
County of San Bernardino

APPROVED (CONSENT CALENDAR)

Moved: Robert A. Lovingood Seconded: Josie Gonzales
Ayes: Robert A. Lovingood, Janice Rutherford, Curt Hagman, Josie Gonzales
Absent: Dawn Rowe

Lynna Monell, CLERK OF THE BOARD

BY _____
DATED: July 14, 2020

cc: ARMC- Gilbert w/agree
Contractor- C/O ARMC w/agree
File- w/agree

la 07/16/2020