

Legislation Text

File #: 3665, Agenda Item #: 17

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

February 9, 2021

# <u>FROM</u> WILLIAM L. GILBERT, Director, Arrowhead Regional Medical Center

## **SUBJECT**

Delegation of Authority to Execute Nondisclosure Agreements Involving Arrowhead Regional Medical Center for the Limited Purpose of Determining Whether to Participate in Clinical Trials

## RECOMMENDATION(S)

Delegate to Hospital Director or the County Chief Executive Officer the authority to execute nondisclosure agreements on behalf of Arrowhead Regional Medical Center for the limited purpose of evaluating potential participation by Arrowhead Regional Medical Center in clinical trials, subject to review by County Counsel. (Presenter: William L. Gilbert, Director, 580-6150)

# COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

Create, Maintain and Grow Jobs and Economic Value in the County. 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) as the recommended item is non-financial in nature.

#### BACKGROUND INFORMATION

On December 15, 2020 (Item No. 14), the Board of Supervisors (Board) approved a Master Template for Sponsored Projects Payment Agreement (Master Template) for all future clinical trials through June 30, 2025. Sponsored Projects are presented by multiple corporations and institutions for clinical trials to be performed at no direct cost to the Arrowhead Regional Medical Center (ARMC), with an allowance of 5-9% available for any indirect costs incurred by ARMC. This competitive rate has begun to draw the attention of potential researchers and companies to consider using ARMC along with California University of Science and Medicine (CUSM) and other institutions as a potential site for clinical trials.

Sponsors of clinical trials, including pharmaceutical companies, are naturally protective of providing detailed information about their research protocols and studies. As such, most sponsors of clinical trials require potential clinical trial sites, including ARMC, to sign a nondisclosure agreement before providing details about their study in order for the site to determine whether or not to participate in the study. As ARMC is working more closely with academic institutions such as CUSM and other institutions on research, it is important to timely evaluate and respond to opportunities for these clinical trials. Thus, in order for ARMC to properly

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evaluate the appropriateness of a particular study for the patients that are served, ARMC would need to expeditiously execute a nondisclosure agreement to gain access to the needed information. Significant delays in executing the nondisclosure agreements generally result in the sponsors of clinical trials moving on to other potential interested sites.

In order to respond in a timely fashion to clinical trial inquiries, ARMC is requesting that the Board delegate authority to the Hospital Director or the County Chief Executive Officer to execute these nondisclosure agreements, subject to review by County Counsel, that are limited to the purpose of allowing ARMC to obtain information about the clinical trials to determine whether or not ARMC would like to participate in them. ARMC would limit the number of individuals with access to any confidential information to the minimum number necessary to make a thorough assessment for the potential benefits for the clinical trial. If after reviewing the study details ARMC seeks to participate in the study, ARMC would seek Board approval of any clinical trial participation agreement.

## PROCUREMENT

Not Applicable.

## **REVIEW BY OTHERS**

This item has been reviewed by County Counsel (Charles Phan, Deputy County Counsel, 387-5465) on January 20, 2021; ARMC Finance (Chen Wu, Finance Budget Officer, 580-3165) on January 26 2021; Finance (Amanda Trussell, Principal Administrative Analyst, 387-5423) on January 21, 2021; and County Finance and Administration (Matthew Erickson, County Chief Financial Officer, 387-5423) on January 25, 2021.